

EXHIBIT C

Marc Toggia, M.D.

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. : Master File No.
PELVIC REPAIR SYSTEM : 2:12-MD-
PRODUCTS LIABILITY LITIGATION : MDL 2327
 :
 : JOSEPH R.
THIS DOCUMENT RELATES TO : GOODWIN
THE CASES LISTED BELOW : US DISTRICT
 : JUDGE

Mullins, et al. v. Ethicon, Inc., et al.
2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al.
2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.
2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al.
2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al.
2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al.
2:13-cv-04517
Martinez v. Ethicon, Inc., et al.
2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al.
2:13-cv-07283
Oxley v. Ethicon, Inc., et al.
2:13-cv-10150
Atkins, et al. v. Ethicon, Inc., et al.
2:13-cv-11022
Garcia v. Ethicon, Inc., et al.
2:13-cv-14355

(Caption Continued on Next Page)

- - -

October 2, 2015

VIDEOTAPED DEPOSITION MARC TOGLIA, M.D.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

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1 CAPTION CONTINUED:
2
3 Lowe v. Ethicon, Inc., et al.
4 2:13-cv-14718
5 Dameron, et al. v. Ethicon, Inc., et al.
6 2:13-cv-14799
7 Vanbuskirk, et al. v. Ethicon, Inc., et al.
8 2:13-cv-16183
9 Mullens, et al. v. Ethicon, Inc., et al.
10 2:13-cv-16564
11 Shears, et al. v. Ethicon, Inc., et al.
12 2:13-cv-17012
13 Javins, et al. v. Ethicon, Inc., et al.
14 2:13-cv-18479
15 Barr, et al. v. Ethicon, Inc., et al.
16 2:13-cv-22606
17 Lambert v. Ethicon, Inc., et al.
18 2:13-cv-24393
19 Cook v. Ethicon, Inc., et al.
20 2:13-cv-29260
21 Stevens v. Ethicon, Inc., et al.
22 2:13-cv-29918
23 Harmon v. Ethicon, Inc., et al.
24 2:13-cv-31818
25 Snodgrass v. Ethicon, Inc., et al.
26 2:13-cv-31881
27 Miller v. Ethicon, Inc., et al.
28 2:13-cv-32627
29 Matney, et al. v. Ethicon, Inc., et al.
30 2:14-cv-09195
31 Jones, et al. v. Ethicon, Inc., et al.
32 2:14-cv-09517
33 Humbert v. Ethicon, Inc., et al.
34 2:14-cv-10640
35 Gillum, et al. v. Ethicon, Inc., et al.
36 2:14-cv-12756
37 Whisner, et al. v. Ethicon, Inc., et al.
38 2:14-cv-13023
39 Tomblin v. Ethicon, Inc., et al.
40 2:14-cv-14664
41 Scheppleng v. Ethicon, Inc., et al.
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43 Tyler, et al. v. Ethicon, Inc., et al.
44 2:14-cv-19110
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3 2:14-cv-22079

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4 2:14-cv-24911

Cheshire, et al. v. Ethicon, Inc., et al.

5 2:14-cv-24999

Burgoyne, et al. v. Ethicon, Inc., et al.

6 2:14-cv-28620

Bennett, et al. v. Ethicon, Inc., et al.

7 2:14-cv-29624

8

- - -

9 OCTOBER 2, 2015

- - -

10

11 Videotape deposition of
12 MARC TOGLIA, M.D., taken pursuant to
13 notice, was held at the law offices of
14 Drinker Biddle and Reath, LLP, One Logan
15 Square, 18th and Cherry Streets, Suite 2000,
16 Philadelphia, Pennsylvania 19103,
17 commencing at 1:26 p.m., on the above
18 date, before Amanda Dee Maslynsky-Miller,
19 a Certified Realtime Reporter and Notary
20 Public in and for the State of
21 Pennsylvania.

22

23

24

Marc Toggia, M.D.

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1 APPEARANCES:

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ALSO PRESENT: Gregory Fields, Videographer

17

- - -

18

19

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21

22

23

24

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5 Testimony of: MARC TOGLIA, M.D.

6 By Ms. Thompson 10. 393
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15	Rule 30 and Document	
16	Requests Pursuant to	
17	Rule 34 of Marc	
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19 Question Marked

20 Page Line Page Line Page Line

21 None

22

23

24

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2 (It is hereby stipulated and
3 agreed by and among counsel that
4 sealing, filing and certification
5 are waived; and that all
6 objections, except as to the form
7 of the question, will be reserved
8 until the time of trial.)

9 - - -

10 THE VIDEOGRAPHER: We are
11 now on the record. My name is
12 Gregory Fields. I'm a
13 videographer for Golkow
14 Technologies. Today's date is
15 October 2nd, 2015, and the time is
16 1:26 p.m. This video deposition
17 is being held in Philadelphia,
18 Pennsylvania, in the matter of In
19 Re: Ethicon, U.S. District Court,
20 Southern District of West
21 Virginia. The deponent is Marc
22 Toggia. Counsel will be noted on
23 the stenographic record. The
24 court reporter is Amanda Miller

Marc Toglia, M.D.

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1 and will now swear in the witness.

2 - - -

3 MARC TOGLIA, M.D., after

4 having been duly sworn, was

5 examined and testified as follows:

6 - - -

7 EXAMINATION

8 - - -

9 BY MS. THOMPSON:

10 Q. Dr. Toglia, I'm Margaret
11 Thompson, I represent the plaintiffs in
12 their case against Ethicon.

13 And you understood that --
14 you understand that that's why you're
15 here today?

16 A. Yes, I do.

17 Q. Could you please state your
18 name for the record?

19 A. Yes. Marc Richard Toglia.

20 Q. And what is your occupation,
21 Dr. Toglia?

22 A. I'm a physician.

23 Q. Do you have a specialty?

24 A. Yes. I'm board certified in

Marc Toggia, M.D.

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1 female pelvic medicine and reconstructive
2 surgery.

3 Q. Are you also board certified
4 in OB/GYN?

5 A. That is correct. I'm double
6 board certified.

7 Q. What is your office address
8 currently?

9 A. It's 1098 West Baltimore
10 Pike, Media, Pennsylvania, Healthcare
11 Center 3, Suite 3404.

12 Q. And who is your employer?

13 A. I'm employed by Main Line
14 Healthcare.

15 Q. Do you have an academic
16 appointment as well?

17 A. I have several. I'm an
18 associate professor of obstetrics and
19 gynecology at what we formerly called
20 Thomas Jefferson School of Medicine, is
21 now the Sidney Kimmel School of Medicine.

22 And I'm also an associate
23 professor, clinical associate professor
24 at the Lankenau Institute of Medical

Marc Toggia, M.D.

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1 Research.

2 Q. So am I understanding
3 correctly that you have a private
4 practice as well as your academic
5 appointment?

6 A. Yes.

7 Q. So you're paid by the
8 academic institutions and then you also
9 have -- receive income from your private
10 practice; is that correct?

11 A. There's no financial
12 compensation for the academic
13 appointments.

14 Q. For either --

15 A. For the --

16 Q. -- one of the academic
17 appointments?

18 Okay. So your income, then,
19 is derived strictly from your private
20 practice of urogynecology?

21 A. That is correct.

22 Q. And would you consider that
23 a specialty practice?

24 A. It's a subspecialty

Marc Toggia, M.D.

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1 practice.

2 Q. A subspecialty practice.

3 So you are a referral
4 practice, so to speak?

5 A. Yes. I exclusively take
6 care of women that have urinary
7 incontinence and pelvic floor disorders.

8 Q. And are those patients
9 typically referred to you by other
10 physicians?

11 A. My patients may come from
12 sisters, mothers, former patients, other
13 physicians. The bulk of my practice
14 probably comes from other physicians.

15 Q. And do you do, as part of
16 that subspecialty practice, general GYN
17 as well or restrict it completely to
18 urogynecology?

19 A. I don't consider my practice
20 general gynecology. I mean, occasionally
21 a gynecologist may send me a patient for
22 an opinion that might have a general
23 gynecology, but that's not what I hold
24 myself out as.

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1 **Q.** So, typically, you would not
2 be doing annual checkups, Pap smears,
3 mammograms, birth control, that sort of
4 thing that a general gynecologist might
5 do?

6 MR. SNELL: Hold on.

7 Objection. Compound. Overbroad.

8 Go ahead.

9 THE WITNESS: No.

10 BY MS. THOMPSON:

11 **Q.** And when you're treating a
12 patient for a urogynecological condition,
13 we'll get to what those are a little bit
14 later, and that condition is resolved, do
15 you then send that patient back to their
16 general gynecologist or primary care
17 physician?

18 **A.** Yes.

19 **Q.** And that would be because,
20 one of the reasons, at least, is that
21 physicians don't want to send their
22 patients to a subspecialty and then lose
23 their patients to their care; is that
24 right?

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1 **A.** I don't know that I would
2 agree with that statement. Let me
3 clarify that. I take care of chronic
4 disease.

5 So it's not unusual for us
6 to maintain a lifetime relationship with
7 these patients. But if I understand you
8 correctly, if I were to take care of a
9 specific pelvic floor disorder and that
10 person was to need, say, a mammogram, a
11 Pap smear or some other kind of primary
12 care service, we are not the ones
13 primarily responsible for that, and they
14 would go back to their referring doctor
15 or the doctor of their choosing.

16 **Q.** Understood. And what if the
17 patient's pelvic floor disorder is cured,
18 same thing?

19 **A.** Yes.

20 **Q.** What hospitals do you
21 currently have privileges at?

22 **A.** Currently, I'm privileged at
23 all four of Main Line Healthcare
24 hospitals. The Main Line Healthcare

Marc Toggia, M.D.

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1 hospital system is located in suburban
2 Philadelphia; it consists of Lankenau
3 Medical Center, Bryn Mawr Hospital, Paoli
4 Hospital and Riddle Hospital.

5 Q. And do you do surgeries at
6 all four of those facilities as well?

7 A. No.

8 Q. Which ones do you perform
9 surgeries at?

10 A. I will operate at Riddle
11 Hospital, Paoli Hospital and Lankenau
12 Medical Center. My schedule does not
13 allow me to operate at, say, Bryn Mawr
14 Hospital. Although I have, from time to
15 time, gone through; but I don't consider
16 that to be a hospital that I would use
17 for surgical procedures.

18 Q. Do you have privileges or do
19 surgery at any type of surgical center,
20 freestanding surgical center?

21 A. I do not.

22 Q. So minor surgeries or those
23 that would be output surgeries are done
24 in the hospital as well?

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1 **A.** I think, technically, the
2 outpatient surgical surgeries are on
3 hospital property, but I think that they
4 are designated as -- you know, there's
5 ambulatory surgery.

6 **Q.** Are they on a different
7 floor --

8 **A.** No.

9 **Q.** -- from the main operating
10 room?

11 **A.** It's all -- it's the same.
12 I mean, patients are classified by their
13 status not by physical location.

14 **Q.** Okay. Are you married, Dr.
15 Toggia?

16 **A.** I am.

17 **Q.** Children?

18 **A.** Yes.

19 **Q.** How many?

20 **A.** I have two children.

21 **Q.** What are their ages?

22 MR. SNELL: Not relevant.

23 Don't answer that question.

24 MS. THOMPSON: You're

Marc Toggia, M.D.

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1 instructing him not to answer?

2 MR. SNELL: Yes. That's
3 private. About his children? He
4 came here to give opinions on the
5 defect and the question that, that
6 the judge posed about TVT, not to
7 tell you about his children.

8 MS. THOMPSON: I'm just
9 getting to know him.

10 MR. SNELL: No, that's not
11 appropriate. I don't ask your
12 experts about who their children
13 are and their ages and stuff.
14 That is totally inappropriate.

15 BY MS. THOMPSON:

16 Q. You can go ahead and answer.

17 MS. THOMPSON: Unless you're
18 instructing him not to answer?

19 MR. SNELL: Yes, I'm
20 instructing him not to answer. I
21 think that violates his privacy,
22 is totally outside the scope, is
23 not relevant.

24 MS. THOMPSON: Okay. Object

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1 to form is sufficient.

2 THE WITNESS: Thank you. I

3 appreciate that. And I agree.

4 BY MS. THOMPSON:

5 Q. Have you given previous
6 depositions?

7 A. Yes.

8 Q. How many?

9 A. I honestly couldn't tell you
10 off the top of my head. Probably no more
11 than a dozen. I don't think I've given a
12 deposition in over ten years, to the best
13 of my -- my knowledge.

14 Q. So somewhere in the range of
15 five to twelve, would you ballpark it?

16 A. Yes.

17 Q. And what types of cases were
18 those depositions given in?

19 A. The vast majority of them,
20 if not all of them, were within the realm
21 of female pelvic floor disorders, areas
22 of my expertise, which oftentimes extends
23 into the obstetrical world.

24 Q. So am I correct those would

Marc Toggia, M.D.

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1 be medical malpractice cases?

2 **A.** Most of them are medical
3 malpractice cases.

4 My reason for pausing, I
5 think one actually involved a piercing or
6 tattoo parlor that was involved. And I
7 don't think that's medical malpractice,
8 but there were medical claims.

9 **Q.** And did you testify for the
10 defense or the plaintiffs or a mix in
11 those cases?

12 **A.** I've done a mix.

13 **Q.** Did any of those cases that
14 you have given depositions in relate to
15 mesh products?

16 **A.** To the best of my knowledge,
17 no.

18 **Q.** Dr. Toggia, did you --

19 - - -

20 (Whereupon, Exhibit
21 Toggia-1, Notice of Videotaped
22 Deposition Pursuant to Rule 30 and
23 Document Requests Pursuant to Rule
24 34 of Marc Toggia, M.D., was

Marc Toggia, M.D.

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1 marked for identification.)

2 - - -

3 MS. THOMPSON: We've marked
4 as Exhibit-1 the notice for your
5 deposition today.

6 MR. SNELL: Thank you.

7 BY MS. THOMPSON:

8 Q. Have you had a chance to --

9 MR. SNELL: Let me -- I just
10 want to give him the original,
11 that way the ones don't get mixed
12 up.

13 MS. THOMPSON: Sure. Thank
14 you.

15 BY MS. THOMPSON:

16 Q. Have you had a chance to see
17 this document prior to just now?

18 A. I have.

19 Q. When did you first see this?

20 A. I was given this document,
21 probably, near the end of last week, to
22 the best of my knowledge.

23 Q. And did you see Schedule A,
24 which is attached to the notice of

Marc Toggia, M.D.

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1 deposition?

2 A. Yes.

3 Q. And it asked you to bring,
4 oh, a whole bunch of documents. And I'm
5 not going to go through these
6 individually.

7 But can you just tell me
8 what you brought with you today?

9 A. Yes. To the best of my
10 knowledge, I have brought, as you put it,
11 as a whole bunch of documents, as they
12 relate to Schedule A.

13 Q. And those are contained in
14 the -- some boxes that you brought to the
15 conference room?

16 A. Yes. Some are electronic,
17 the majority of them are copied on paper.

18 Q. And I think Mr. Snell
19 provided me a flash drive with everything
20 that's in the boxes, correct?

21 MR. SNELL: As far as I
22 know. Although, he's brought
23 thumb drives, too.

24 MS. THOMPSON: Okay.

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1 MR. SNELL: So, I mean --
2 and also, I mean, you may want to
3 ask him, but he's done his own
4 research. So he may have stuff
5 that I don't even have.

6 MS. THOMPSON: I think I
7 should do that.

8 BY MS. THOMPSON:

9 Q. Dr. Toggia, could you just
10 go through what you brought here and
11 describe what you have? Not document by
12 document, but generally speaking.

13 A. Generally speaking, I have
14 brought the relevant clinical studies and
15 other published research, as well as the
16 legal documents, including the expert
17 reports and depositions.

18 Q. Did you bring anything with
19 you that is not included on your -- the
20 reliance list that's attached to your
21 report?

22 A. Obviously, I can't claim to
23 have an independent knowledge of every
24 specific element on that list, but to the

Marc Toggia, M.D.

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1 best of my knowledge, I have done my best
2 to comply and everything is -- is as it
3 is listed.

4 MR. SNELL: I will make one
5 note, just for a clean record,
6 too, as he did say, since the time
7 he published his report and his
8 reliance materials list, there
9 have been depositions of your
10 experts. He, obviously, has those
11 and I think he might have even
12 said that.

13 But when she asks you a
14 question you are allowed to take
15 them and look at them and tell her
16 what you reviewed.

17 THE WITNESS: Understood.

18 MS. THOMPSON: And we'll
19 maybe take a brief look at it at
20 the break.

21 MR. SNELL: That's fine. He
22 brought it here, it's up to you.
23 You can look at it, copy it, do
24 whatever you want.

Marc Toggia, M.D.

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1 MS. THOMPSON: I appreciate
2 that.

3 BY MS. THOMPSON:

4 Q. Did you bring any billing
5 records with you today?

6 MR. SNELL: I have those. I
7 have them somewhere.

8 Let's go off the record for
9 a second.

10 VIDEO TECHNICIAN: We are
11 off the record. The time is 1:38
12 p.m.

13 - - -

14 (Whereupon, a discussion off
15 the record occurred.)

16 - - -

17 VIDEO TECHNICIAN: We are
18 back on the video record.

19 BY MS. THOMPSON:

20 Q. Dr. Toggia, I think you
21 brought your report that you prepared in
22 this case --

23 A. Yes.

24 Q. -- is that correct?

Marc Toglia, M.D.

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1 - - -

2 (Whereupon, Exhibit
3 Toglia-2, Expert Report of Marc R.
4 Toglia, M.D., was marked for
5 identification.)

6 - - -

7 BY MS. THOMPSON:

8 Q. And we have marked that as
9 Exhibit Number 2.

10 I believe you have your own
11 copy as well?

12 A. I do.

13 Q. Do you have any notes on
14 your copy that you brought with you?

15 A. I mean, I've got some
16 underlines in pencil. I may have made a
17 spelling correction. I don't have any
18 prose of any kind in there.

19 Q. There's a curriculum vitae
20 attached to that report --

21 A. Yes.

22 Q. -- as you recall.

23 Is that a current C.V.?

24 A. It is.

Marc Toggia, M.D.

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1 **Q.** Are there any additions that
2 you would make to that, sitting here
3 today --

4 **A.** No.

5 **Q.** -- that you can think of?

6 MS. THOMPSON: So Exhibit-2
7 will be the report and the -- with
8 the C.V.

9 - - -

10 (Whereupon, Exhibit
11 Toggia-3, Invoices, was marked for
12 identification.)

13 - - -

14 BY MS. THOMPSON:

15 **Q.** And it looks like you also
16 brought, today, two bills or invoices for
17 your work in this case, and we've marked
18 that as Exhibit Number 3.

19 **A.** Thank you.

20 **Q.** Do those look familiar?

21 **A.** Yes.

22 **Q.** And the last date on the
23 invoice is September 24th.

24 Can you approximate how many

Marc Toggia, M.D.

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1 hours you have worked on this case since
2 September 24th? That would be in the
3 last week or so.

4 **A.** Would it be sufficient if I
5 told you that I've probably done -- used
6 a total of about 50 hours in total?

7 **Q.** So 50 hours total on this
8 case to date?

9 **A.** 50 hours --

10 **Q.** Approximately?

11 **A.** Approximately 50 hours of
12 work on this case.

13 **Q.** How many hours did you spend
14 preparing your report, approximately?

15 **A.** Approximately 23 years and
16 50 hours.

17 And the reason why I say
18 that, counselor, is that most of the
19 material that I have reviewed, I have
20 reviewed over the span of my career. And
21 that would include, perhaps, reviewing it
22 prior to being published, watching it be
23 presented at meetings, having read it
24 over and over for my own personal, you

Marc Toggia, M.D.

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1 know, knowledge and interest.

2 And, certainly, many of
3 these articles relate to the subspecialty
4 board certification.

5 Q. But you haven't billed
6 Ethicon for 23 years, correct?

7 A. I've told you that I've
8 billed them for 50 hours, counselor,
9 right. In formulating my opinion.

10 Q. I'm just trying to break --
11 break it down a little bit --

12 A. Sure.

13 Q. -- and try to understand how
14 much of that 50 hours was actually
15 preparing your report.

16 And if you can't -- if
17 you're not -- unable to do that, that's
18 fine.

19 A. In preparing the report, it
20 probably is, both of these, 10 hours plus
21 33 hours, 43 hours; and the difference is
22 probably split between preparing for the
23 deposition and additional work finalizing
24 the report.

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1 **Q.** So that would include review
2 of literature, for instance?

3 **A.** Correct.

4 **Q.** When were you first
5 contacted to serve as an expert in this
6 case?

7 **A.** If memory serves me right,
8 it was some time in August.

9 **Q.** And do you have any
10 correspondence regarding that initial
11 contact?

12 **A.** I do not.

13 **Q.** Was it a phone call?

14 **A.** Correct.

15 **Q.** From Mr. Snell or another
16 attorney?

17 **A.** From Mr. Snell.

18 **Q.** And what did Mr. Snell ask
19 you to do?

20 **A.** Mr. Snell apprised me to the
21 existence of the case and that he needed
22 to retain an expert to specifically
23 comment on the claims as they relate to
24 the safety, the design of the TVT

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1 product.

2 Q. Did he provide you with
3 materials to review?

4 A. Mr. Snell provided me with,
5 I believe, the original complaint and, of
6 course, my access to the internal
7 documents from the company and from the
8 plaintiffs' experts and the exhibits.

9 Q. Did he also provide you with
10 literature?

11 A. Yes.

12 Q. And so on your reliance list
13 that's attached to your report, does that
14 include the literature that Mr. Snell
15 provided you?

16 A. To be completely honest with
17 you, there was very little on that list
18 that I was not already familiar with.

19 Q. So you were familiar with
20 the majority of the articles on the list.

21 But the list was provided by
22 counsel; is that correct?

23 MR. SNELL: Correct, yes.

24 THE WITNESS: Yes.

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1 MR. SNELL: I will say that
2 I -- I provided this list.

3 MS. THOMPSON: Fair enough.

4 BY MS. THOMPSON:

5 Q. And these were the articles
6 that Mr. Snell provided you with as well?

7 A. Yes.

8 MR. SNELL: I will make one
9 note for the record. He sent
10 articles and things to me that I
11 told paralegals to put on this
12 list, okay?

13 MS. THOMPSON: Fair enough.

14 MR. SNELL: So I tried to
15 capture whatever he went out and
16 found, just so you would have it.

17 BY MS. THOMPSON:

18 Q. So the list would include
19 articles that Mr. Snell provided you,
20 articles that you thought were relevant
21 that you sent back to him, and those were
22 just --

23 A. Right. And to be clear,
24 there was a large degree of duplication

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1 between things that I had already had in
2 my possession and things that were on his
3 list.

4 Q. And I actually noticed that
5 there were some duplications on the list
6 itself, because of minor variations in
7 the citation or whatever.

8 And, I guess, that might
9 have been the case on some of those,
10 correct?

11 A. Counselor, I'm sorry, I'm
12 not -- I'm not familiar with what,
13 specifically, you're referring to or what
14 you're --

15 Q. Okay. Are all the opinions
16 that you intend to provide at trial
17 contained in this report?

18 A. Yes. With the exception of
19 anything that I might discover, you know,
20 between now and then that might be of
21 relevance.

22 Q. Okay. And you mentioned
23 depositions that you reviewed. And some
24 of those are listed on the reliance list,

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1 if you look on the last page.

2 Are there any that come to
3 mind that you've reviewed in addition to
4 these?

5 **A.** I'm not sure that I have
6 what you're referring to as a reliance
7 page.

8 **Q.** Attached to your report.

9 **A.** Oh, I'm sorry.

10 Yes, I would say the ones
11 that come to mind would be the
12 deposition -- the recent depositions of
13 the plaintiffs' experts, which would
14 include Dr. Blaivas, Dr. Rosenzweig and
15 Dr. Elliott.

16 **Q.** So the depositions of Drs.
17 Blaivas, Rosenzweig and Elliott are in
18 addition to the reports listed here?

19 **A.** Correct.

20 MR. SNELL: I'll make a
21 note, for the record, that he may
22 have opinions regarding those
23 expert depositions.

24 BY MS. THOMPSON:

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1 **Q.** Do you have any opinions
2 related to the expert depositions that
3 you reviewed that you can relate to me at
4 this time?

5 **A.** I do.

6 **Q.** Why don't you go ahead --
7 that are different from what you have in
8 your report?

9 **A.** I don't know that I would
10 say different. They would be, maybe,
11 perhaps, in addition. That I might have
12 opinions in addition to what I may have
13 expressed in the report, if that makes
14 sense to you.

15 **Q.** Sure. Why don't you go
16 ahead and, to the best of your ability,
17 give me those additional opinions now?

18 **A.** Where would you like me to
19 start?

20 **Q.** Wherever you want to start.

21 MR. SNELL: You can -- do
22 you want the depositions?

23 THE WITNESS: Would it be
24 helpful for you, counselor, if,

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1 perhaps, I explain to you my
2 methodology, as far as what --
3 what I did in terms of formulating
4 the opinion and what I found, what
5 I -- what I was told was sort of
6 my charge, so to speak?

7 BY MS. THOMPSON:

8 **Q.** Sure.

9 **A.** I think that will just make
10 what I'm about to say more -- sort of
11 more relevant.

12 So it was my understanding
13 that I was to formulate an opinion
14 whether or not the design of the TVT was
15 reasonably safe for its intended use for
16 the treatment of stress incontinence in
17 women versus whether or not it was
18 defective in its design.

19 In formulating my opinion, I
20 looked at the high-quality studies. By
21 that I mean those that we would consider
22 to be Level 1 evidence, things such as
23 randomized control trials, systematic
24 reviews, the prospective longitudinal

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1 registry trials. All of these would
2 constitute what we would consider to be
3 Level 1 scientific evidence.

4 From there, I reviewed the
5 published position statements from the
6 relevant specialty societies. And those
7 would be sort of the high-quality data
8 that I used to formulate my opinion.

9 There were additional pieces
10 of works, such as those exhibits -- I
11 don't always know the legal term for
12 these things -- that were provided by
13 your experts, by the plaintiffs' experts
14 that, of course, I would have looked at
15 and considered, because, obviously, they
16 were relevant in that regard.

17 I will tell you, just to be
18 clear, that, in general, things like
19 bench research, in vitro studies, case
20 series, we consider those to be Level
21 5 -- expert opinion, Level 5 studies.
22 And those, typically, are not very
23 relevant or scientifically meaningful,
24 especially when Level 1 evidence exists.

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1 And so those things, because
2 of their severe limitations, you can
3 never derive clinical inference or
4 medical conclusions, because the evidence
5 is so weak.

6 So while I am familiar and
7 have reviewed those studies and
8 documentations, typically, they don't
9 factor into the formulation of an
10 opinion.

11 In that regard, I would say,
12 as a general statement, I was struck by
13 the fact that all three of the expert
14 reports that I reviewed, and I'm
15 specifically referring to those by Dr.
16 Rosenzweig, Blaivas and Elliott, that
17 they were significantly devoid of similar
18 high-quality Level 1 evidence studies and
19 seemed to spend the majority of their
20 time looking at far less clinically
21 relevant Level 5 studies, such as animal
22 studies, bench research, in vitro
23 studies, unpublished observations, as
24 well as personal experience and expert

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1 opinion.

2 So as a general statement,
3 my additional opinion is that, you know,
4 the majority of what I've read from these
5 individuals is not of very high
6 scientific quality.

7 And I think that they have,
8 if I can be completely honest,
9 misrepresented data from levels of
10 evidence that do not allow you to make
11 clinical inference or draw conclusions
12 specifically as it would relate to the
13 design and safety of the TVT device and
14 specifically to its intended use for the
15 treatment of female stress incontinence.

16 Q. Let's go ahead and get to
17 the additional opinions that you have,
18 with that background.

19 A. Yes.

20 Q. What are those additional
21 opinions?

22 A. I think I've given you
23 what -- what those opinions are. I mean,
24 if you have specific questions, I'm more

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1 than happy to discuss those with you.

2 **Q.** All right. So it sounds
3 like the additional opinion that you're
4 giving are that the plaintiff experts'
5 reports are devoid of high-quality
6 studies?

7 MR. SNELL: Objection. He
8 told you a lot more than that.

9 THE WITNESS: Yes. I don't
10 think --

11 BY MS. THOMPSON:

12 **Q.** I think that's --

13 **A.** -- I can simplify it into a
14 single sentence.

15 **Q.** Now, you'll agree with me
16 that a position statement is not a
17 scientific study, correct?

18 **A.** A scientific -- I would not
19 agree with that statement. And let me
20 clarify.

21 A position statement is a
22 summary statement typically based upon a
23 systematic review or independent analysis
24 of Level 1 data.

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1 **Q.** But it's not a scientific
2 piece of literature? It's not peer
3 reviewed, is it?

4 MR. SNELL: Objection.
5 Asked and answered.

6 THE WITNESS: I disagree.
7 They -- they are peer reviewed.
8 All position statements are
9 formulated and then reviewed prior
10 to publication. In fact, the
11 majority of them, for example,
12 you'll see, are published in
13 peer-reviewed journals. You
14 cannot be published in a
15 peer-reviewed journal unless you
16 are peer reviewed.

17 BY MS. THOMPSON:

18 **Q.** Okay. Well, let's just
19 consider the AUGS position statement on
20 midurethral slings.

21 You're familiar with that
22 document, correct?

23 **A.** Yes. I have that document
24 here in my possession.

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1 **Q.** Do you know why that was
2 prepared?

3 **A.** Do I know why? Can you --
4 I'm not sure if I understand what
5 you're -- what you're meaning.

6 **Q.** What was the purpose for the
7 preparation of that position statement by
8 AUGS?

9 **A.** The AUGS position statement
10 was -- was created to, as I stated, to
11 provide a summary statement based upon
12 high-quality scientific evidence in light
13 of -- I'm sorry for putting this,
14 unfounded claims regarding the design
15 defects and similar type statements.

16 **Q.** So if I told you that the
17 purpose, the reason that the AUGS
18 position statement was written was to use
19 in courtrooms, in litigation, would you
20 have any reason to doubt that?

21 **A.** Yes.

22 MR. SNELL: Hold on. Let
23 me -- let me -- you have to give
24 me a chance to object.

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1 THE WITNESS: Sorry.

2 MR. SNELL: Objection.

3 Lacks foundation.

4 Go ahead.

5 THE WITNESS: That

6 absolutely was not the reason.

7 BY MS. THOMPSON:

8 Q. And you're confident of
9 that?

10 A. I am confident of that, yes.

11 Q. Okay. And are you familiar
12 with the authors of that position
13 statement?

14 A. Yes.

15 Q. Are you familiar with the
16 authors' industry ties?

17 A. I can't tell you that I know
18 in any great detail what their ties are.

19 Q. If I told you that they all
20 have conflicts of interest regarding
21 their financial relationship with
22 industry, would you have any reason to
23 doubt that?

24 A. Yes.

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1 MR. SNELL: Hold on. Let
2 me -- you have to give me -- these
3 are totally without -- objection.
4 Lacks foundation. Misstates
5 evidence.

6 Go ahead.

7 THE WITNESS: I would not
8 believe what you're saying. Or I
9 don't believe what you're saying.

10 BY MS. THOMPSON:

11 Q. Is there anywhere in that
12 two-page position statement that mentions
13 complications or risks associated with
14 midurethral slings?

15 A. May I refer to it?

16 MR. SNELL: Of course.

17 MS. THOMPSON: Sure.

18 MR. SNELL: You can always
19 get it out.

20 That goes for any document
21 she asks you about.

22 THE WITNESS: Of course, it
23 has to be the one that's all the
24 way at the back.

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1 MR. SNELL: Just so I'm
2 clear on the record, which one are
3 you talking about?

4 MS. THOMPSON: The AUGS
5 position statement on midurethral
6 slings.

7 MR. SNELL: There's a
8 couple.

9 THE WITNESS: There's one.
10 There's --

11 MS. THOMPSON: I'm only
12 familiar with one position
13 statement.

14 - - -

15 (Whereupon, a discussion off
16 the record occurred.)

17 - - -

18 THE WITNESS: Counselor,
19 thank you for waiting.

20 I have in front of me the
21 AUGS/SUFU position statement on
22 mesh midurethral slings. I would
23 ask that you repeat the question
24 to me, please.

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1 BY MS. THOMPSON:

2 Q. The question is, in this,
3 actually, three-page position statement,
4 is there any mention of complications or
5 risks associated with midurethral slings?

6 A. I believe that the purpose
7 of the position statement was to
8 acknowledge the fact that the midurethral
9 sling was recognized as the worldwide
10 standard of care and that the procedure
11 was felt to be safe and effective.

12 I don't believe that this
13 was a document that was intended to
14 address the question that you're asking
15 me.

16 Q. So the answer is no?

17 MR. SNELL: Objection.

18 Misstates.

19 MS. THOMPSON: Well, it's a
20 yes-or-no question.

21 BY MS. THOMPSON:

22 Q. Is there any mention of
23 complications or risks in this three-page
24 document?

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1 MR. SNELL: He just told you
2 it discussed the safety.

3 MS. THOMPSON: He said --
4 okay.

5 BY MS. THOMPSON:

6 Q. Let's -- show me where it
7 discusses the safety.

8 A. Counselor, on Page 2, under
9 Number 4, The FDA has clearly stated that
10 polypropylene midurethral sling is safe
11 and effective in the treatment of stress
12 urinary incontinence.

13 In this document it is
14 explicitly stated, That the FDA -- and
15 I'll just paraphrase, The safety and
16 effectiveness of multi-incision slings is
17 well established in clinical trials.

18 Q. It still doesn't -- it says
19 it's safe.

20 Does it discuss
21 complications?

22 A. Counselor, the question that
23 you asked me is whether or not it was
24 safe. I answered the question.

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1 **Q.** I said -- there's a
2 discussion of safety. That, to me, is
3 not a discussion of safety.

4 MR. SNELL: Objection. That
5 is not a question. Move to strike
6 the attorney comment.

7 BY MS. THOMPSON:

8 **Q.** Are there any complications
9 of midurethral slings discussed in this
10 position paper?

11 **A.** Again, that was not the
12 purpose of the paper. So I am not
13 surprised that there would not be a
14 specific discussion of that in that
15 particular paper.

16 But, again, that was one of
17 a series of papers that AUGS published on
18 that.

19 **Q.** So your position is that the
20 purpose of this position statement by
21 AUGS and SUFU was to report on the
22 clinical studies related to midurethral
23 slings, but it was not necessary to
24 comment on any complications or risks

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1 associated; is that your testimony?

2 MR. SNELL: Objection.

3 THE WITNESS: That's

4 not what I --

5 MR. SNELL: Hold on.

6 Objection. Misstates testimony.

7 MS. THOMPSON: I'm asking if

8 that's his testimony. If it's

9 not, he can tell me it's not.

10 THE WITNESS: It is not my

11 testimony, counselor.

12 Again, to be clear, a

13 position statement is exactly

14 that, it's a statement on a

15 position. And the position taken

16 here was specifically and simply,

17 midurethral slings are recognized

18 as the worldwide standard of care

19 for the treatment of stress

20 urinary incontinence.

21 The statement is that the

22 procedure is safe, effective and

23 has improved the quality of life

24 for millions of women.

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1 BY MS. THOMPSON:

2 Q. So, then, a position
3 statement is an opinion, correct?

4 A. A position statement is an
5 opinion.

6 Q. And I don't think we ever
7 answered my question if there were any
8 complications discussed, but I'd like for
9 you to answer that yes or no.

10 Were -- are any
11 complications discussed in the position
12 statement?

13 MR. SNELL: Objection.

14 Asked and answered.

15 MS. THOMPSON: He has not
16 answered it.

17 THE WITNESS: That wasn't
18 the purpose of the -- of the
19 position statement.

20 BY MS. THOMPSON:

21 Q. I didn't ask about the
22 purpose.

23 I asked you, are
24 complications or risks discussed in this

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1 position statement?

2 **A.** They are not discussed in
3 the position statement.

4 **Q.** Thank you.

5 Let's go back to the
6 Schedule A on the notice of deposition.
7 I want to ask you just about a handful of
8 items to see if you brought them or had
9 them in your possession.

10 Number 13, do you -- did you
11 bring any Ethicon products in your
12 possession?

13 **A.** I have no Ethicon products
14 in my possession.

15 **Q.** The documents or
16 communications relating to presentations
17 or lectures given to you concerning
18 pelvic mesh, pelvic organ prolapse or
19 stress urinary incontinence, did you
20 bring those items with you?

21 **A.** I'm sorry, I'm not -- I'm
22 not --

23 **Q.** Number 16. Sorry.

24 **A.** Okay. I'm sorry. The

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1 reason I was confused, you didn't -- you
2 didn't say that I used.

3 You want -- are you -- are
4 you asking about any presentation that is
5 about pelvic mesh or are you specifically
6 saying presentations that I contributed
7 or I presented?

8 Q. Given or contributed to by
9 you.

10 A. And the question was, I'm
11 sorry, did I bring?

12 Q. Did you bring any of those
13 documents relating to presentations or
14 lectures given or contributed to by you?

15 A. I don't -- I don't -- I
16 don't recall that I have those in my -- I
17 don't have an independent recollection of
18 those being in my possession.

19 Q. Do you have PowerPoints
20 relating to stress incontinence or mesh
21 products?

22 A. In general or with me?

23 Q. In general first.

24 A. Yes. I have PowerPoint -- I

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1 have given PowerPoint presentations in
2 the past. I do not have any with me.

3 Q. Could you get those for us
4 and provide those to Mr. Snell?

5 A. I don't -- I don't know that
6 I have all presentations that I've ever
7 given.

8 Q. Could you provide to Mr.
9 Snell everything that you have relating
10 to these three areas?

11 A. I'm sorry, can you -- let me
12 just -- I just want to make sure that I'm
13 clear as far as what three areas.

14 Q. Pelvic mesh, pelvic organ
15 prolapse and stress urinary incontinence.

16 A. Counselor, I'm sorry, can
17 you tell me why pelvic mesh is relevant
18 to an analysis of the -- of the TVT
19 design? Because that's a completely
20 different disease state.

21 Q. I'm not talking about the
22 disease state. And I ask the questions.
23 But I'm happy to answer that.

24 A. Yes.

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1 **Q.** The TVT uses the same
2 material that's used in other pelvic mesh
3 products, correct?

4 MR. SNELL: Objection.
5 Overbroad.

6 THE WITNESS: That was not
7 part of my analysis. My analysis
8 was on the TVT design and safety.

9 BY MS. THOMPSON:

10 **Q.** But I'm asking the
11 questions. And I'm asking you the
12 question.

13 Does the TVT use the same
14 material that's used in other pelvic mesh
15 devices?

16 **A.** The base --

17 MR. SNELL: Same objection.

18 THE WITNESS: The base
19 material, they're both based upon
20 macroporous polypropylene mesh.
21 I'm not sure I would -- and
22 there's a wide variety of
23 fabrication and materials used.

24 I don't want you to think

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1 that I think that, say, the mesh
2 that we use for pelvic organ
3 prolapse is simply the exact TVT
4 material expanded to a larger
5 size.

6 BY MS. THOMPSON:

7 **Q.** Well, let me ask you this:
8 What is the TVT material?

9 **A.** The Gynecare TVT™ is a Amid
10 Type I macroporous polypropylene mesh
11 that is of a knitted design.

12 **Q.** Is it lightweight or
13 heavyweight?

14 **A.** In my opinion, it is a
15 lightweight mesh.

16 Although I would say this,
17 weight of mesh is dependent upon the
18 volume or surface area. And I don't
19 really think that anybody -- excuse me, I
20 don't think that I could classify it
21 based on weight, given the fact that it's
22 a 1.1 centimeter strip of material.

23 So the short answer is that
24 it's lightweight. I am -- I am

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1 clarifying that to say that, you know,
2 weight is a descriptor that's really
3 based upon surface area or volume. And
4 there's such a small volume of material
5 that we're talking about that I don't
6 know that anybody would specifically
7 state that that material was of a
8 specific weight.

9 Q. So it's your opinion that
10 you can't determine whether the mesh used
11 in the Gynecare TVT™ is heavyweight or
12 lightweight?

13 MR. SNELL: Objection.
14 Misstates.

15 THE WITNESS: That's not
16 what I said.

17 BY MS. THOMPSON:

18 Q. Then -- so someone can do it
19 but you can't, is that the answer?

20 MR. SNELL: Same objection.

21 THE WITNESS: I didn't say
22 that either.

23 BY MS. THOMPSON:

24 Q. Okay. My question, then,

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1 is, is the mesh used in the Gynecare
2 TVT™ lightweight or heavyweight; choose
3 one of the two, or can't be determined?

4 **A.** The TVT -- the TVT device, I
5 would consider to be a lightweight
6 macroporous polypropylene mesh, with the
7 understanding that mesh weight,
8 technically, you have to consider the
9 volume of the material.

10 **Q.** Did Ethicon show you any
11 documents that described the TVT mesh as
12 not being macroporous and lightweight?

13 **A.** The documentation that I am
14 familiar with would support the -- what I
15 have said, TVT is a lightweight
16 macroporous mesh.

17 **Q.** And what are the documents
18 that you're using to base that opinion
19 on?

20 **A.** Everything that we are
21 referencing in the report, the materials
22 that we have included here today.

23 **Q.** Can you be more specific
24 than that?

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1 **A.** It would take -- it would
2 take hours to go over all of those
3 things.

4 **Q.** Have you seen any Ethicon
5 documents stating that the Gynecare TVTTM
6 is large pore lightweight?

7 **A.** I -- the TVT is lightweight
8 and large pore.

9 **Q.** And you're confident about
10 that position?

11 **A.** Counselor, I'm extremely
12 confident in that statement.

13 **Q.** I want to talk a little bit
14 about your use of mesh products,
15 including Ethicon products.

16 I believe in your report you
17 stated that you began using the TVT in
18 1999; is that correct?

19 **A.** Yes.

20 **Q.** And were you trained by
21 Ethicon in the use of that device?

22 **A.** I was.

23 **Q.** Do you remember who you were
24 trained by?

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1 **A.** I do.

2 **Q.** Who is that?

3 **A.** Dr. Vince Lucente, one of my
4 colleagues.

5 **Q.** And that training took place
6 in early 1999; is that correct?

7 **A.** I would be guessing, but I
8 believe it might have been in May of
9 1999. But I honestly can't tell you
10 when -- when within the year it was.

11 **Q.** And was that training done
12 formally through Ethicon or did Dr.
13 Lucente provide a more informal
14 preceptorship to you?

15 MR. SNELL: Objection.
16 Vague.

17 THE WITNESS: Dr. Lucente
18 and I are close colleagues. It is
19 not unusual for us to communicate
20 and get together and work
21 together.

22 So, to be honest, it's --
23 Ethicon did not come to me and
24 say, we want you to go work with

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1 Dr. Lucente. Dr. Lucente and I
2 were having a conversation about
3 things that he was working on. I
4 asked if I could come up and
5 become involved.

6 I'm sure that there may or
7 may not have been a relationship,
8 at that time, between Ethicon and
9 Dr. Lucente regarding my training.
10 I certainly was not aware of that
11 directly. This is something that
12 Dr. Lucente and I, and other
13 colleagues, would do for each
14 other routinely.

15 BY MS. THOMPSON:

16 Q. Sure. So you didn't attend
17 an Ethicon sponsored training session; is
18 that what you're saying?

19 MR. SNELL: Objection to
20 form.

21 THE WITNESS: To the best of
22 my recollection, there may or may
23 not have been a presentation
24 given. My independent

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1 recollection is that he and I
2 performed maybe four or five cases
3 together.

4 But I honestly can't -- I
5 can't tell you whether there was a
6 formal or informal -- to be honest
7 with you, given our relationships,
8 those lines are blurred.

9 BY MS. THOMPSON:

10 Q. Sure. And I understand.

11 A. Yes.

12 Q. I'm just trying to find out
13 whether you were given the Ethicon oral
14 presentation, for example, on the new
15 device --

16 MR. SNELL: Objection.

17 BY MS. THOMPSON:

18 Q. -- by an Ethicon
19 representative.

20 MR. SNELL: Objection.

21 Vague.

22 THE WITNESS: Not to my
23 knowledge.

24 BY MS. THOMPSON:

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1 **Q.** And did you participate in
2 cadaver labs sponsored by Ethicon?

3 **A.** Note, in the next ten years,
4 I did a tremendous amount, or a variety
5 of different things. I'm just not clear
6 if we're referring to that one incidence
7 or -- I mean, this was not a one-time
8 experience.

9 **Q.** Understood. I'm referring
10 now to your training and I think we'll
11 get, later, the training that you gave
12 other doctors.

13 **A.** Right.

14 **Q.** But it sounds like, to me,
15 and correct me if I'm wrong, you at least
16 don't recall attending a formal training
17 program sponsored by Ethicon --

18 **A.** No, no.

19 MR. SNELL: Objection.

20 Overbroad.

21 BY MS. THOMPSON:

22 **Q.** -- prior to using the TVT.

23 MR. SNELL: Same objection.

24 THE WITNESS: Maybe I

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1 didn't -- maybe I wasn't clear.

2 I thought we were talking
3 about what my first exposure was.
4 But, of course, I had formal
5 training from Ethicon prior to me
6 independently performing the
7 procedure in my practice.

8 What I don't recall, and I'm
9 really don't mean to be vague, is
10 whether I did that training first
11 and then worked with Dr. Lucente,
12 whether they may have -- may have
13 simultaneously occurred, or
14 whether I first looked at the
15 procedure with Dr. Lucente and
16 then had the formal training.

17 I do know that prior to
18 doing the training with Dr.
19 Lucente, I did consult with the
20 company prior to the procedure's
21 launch and received education at
22 that level.

23 BY MS. THOMPSON:

24 Q. Okay. Fair enough. So

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1 sounds like you had both, formal training
2 from the company --

3 A. Yes.

4 Q. -- and a preceptorship or
5 whatever you want to call --

6 A. I wouldn't call it a
7 preceptorship, but I had -- I mean,
8 surgeons learn procedures from other
9 surgeons.

10 Q. Sure.

11 A. Right.

12 Q. And do you still use the
13 Retropubic TVT device in your practice?

14 A. Yes, I do.

15 Q. Do you use other retropubic
16 sling products?

17 A. I do not.

18 Q. So exclusive to TVT is what
19 you're using now for a retropubic am
20 synthetic sling?

21 A. I have experience with a
22 wide variety of devices. But if you were
23 to come to me as a patient and we had
24 determined that an anti-incontinence

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1 procedure was appropriate, then the
2 retropubic TVT is, 95 percent of the
3 times, the retropubic procedure or
4 midurethral-sling-based procedure that I
5 would use.

6 Q. Are you doing, currently,
7 any transobturator slings?

8 A. I do do transobturator
9 slings.

10 Q. What percentage of your
11 practice, currently, is retropubic and
12 what percentage transobturator?

13 A. It's probably 95 percent
14 retropubic and about 5 percent at the
15 present time. It has varied over time.

16 Q. And over the years, how many
17 TVT or TVT Exact® products have you used?

18 A. By my best estimates, I
19 would say 2,500 TVT procedures, give me a
20 wide margin of error of probably 300 in
21 either direction, perhaps.

22 Q. How do you keep track of
23 which products you use?

24 A. I have a very good memory.

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1 **Q.** So if I wanted to ask you
2 exactly how many of a given product you
3 have used, could you tell me?

4 **A.** I could give you an
5 approximate ballpark.

6 **Q.** And how would you do that?

7 **A.** Through a variety of
8 methods. But, as I said, I've got a
9 pretty good idea mentally. If you ask me
10 how many TVT-Securs I did, I would tell
11 you 60.

12 **Q.** And that would come from
13 your memory, correct?

14 **A.** My memory. I'd have to go
15 through some office records, some
16 documentation elsewhere.

17 **Q.** So what office records would
18 you go through?

19 **A.** We have billing data. You
20 know, I am not telling you that these are
21 things that are readily available to me,
22 if you asked me, can I see this in the
23 next, you know, hour or day.

24 But, certainly, there are --

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1 there are internal things that we
2 could -- you know, databases that would
3 contain such records.

4 **Q.** So you could go to your
5 billing records and tell me whether a TVT
6 or TVT Exact® was used?

7 **A.** No, I don't think I could do
8 it through billing records, obviously.
9 Billing records wouldn't tell me that.

10 **Q.** What other records would you
11 use?

12 **A.** We would have to pull the
13 charts on every patient. And every --
14 very procedure that's done carries an
15 implant record. And so someone would sit
16 there with approximately 2,500 charts and
17 go through the implant records.

18 And by looking at the lot
19 number or model number, we would be able
20 to tell -- I mean, obviously, the Exacts®
21 would all be labeled as such and the TVTs
22 and the Obturator would be labeled as
23 such.

24 **Q.** And is that what we would

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1 have to do to determine which -- what
2 complications experienced as well?

3 A. No.

4 Q. How would we be able to
5 determine what complications patients
6 have experienced?

7 MR. SNELL: Objection.

8 Overbroad. Are you talking about
9 his patients?

10 MS. THOMPSON: Yes.

11 THE WITNESS: I'm sorry,
12 what was your question? I'm not
13 sure I understood it.

14 BY MS. THOMPSON:

15 Q. How would we determine --

16 A. You seem -- you seemed to
17 have switched gears.

18 Q. Well, I was just interested
19 in determining how you figured out what
20 product was used. And I'm also
21 interested in how you figure out what
22 complications patients experienced.

23 And I'm asking you, how
24 would we determine that?

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1 **A.** I'm sorry, that's not what
2 you asked me originally. That's a
3 whole -- I would have to start from
4 scratch to --

5 **Q.** Okay.

6 **A.** You've asked me how -- you
7 asked me what products have I used and
8 what percentage of products that I've
9 used and how it would be that I would
10 determine that number of products.

11 **Q.** Yes.

12 Now I'm asking you, how
13 would you determine which complications
14 occurred with various products?

15 **A.** I would have to sit down and
16 try and figure that out, counselor. I
17 can't tell you off the top of my head
18 that I have an accurate way of -- I mean,
19 there may be ways, through the billing
20 system, to capture certain complications
21 based upon -- by diagnosis codes.

22 **Q.** Let's go through other
23 Ethicon products.

24 Did you use the TVT-O at

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1 some point?

2 A. I did.

3 Q. About how many TVT-Os did
4 you place?

5 A. Approximately 2 to 300.

6 Q. And when did you start using
7 the TVT-O?

8 A. To the best of my knowledge,
9 I can't remember when -- the product
10 launch was in 2005 or 2002? Whenever the
11 product was launched, roughly about when
12 I had used the TVT-O.

13 Q. And how did you learn about
14 the TVT-O?

15 A. By that point in time, I
16 was -- you know, we -- we attend certain
17 scientific meetings, publications, the
18 usual things that we do in the course of
19 our -- of our practice, my role reviewing
20 manuscripts for publications, my role as
21 an editor of journals.

22 I mean, there's a wide range
23 of ways that topics like this were
24 introduced to us.

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1 **Q.** Did you get information from
2 sales reps?

3 **A.** On the TVT-O? Eventually.
4 I can't tell you that that was maybe
5 my -- if that was my first exposure or
6 not. To be completely frank, at my level
7 of involvement with the company, sales
8 reps are not a -- that's not a source
9 that I would utilize a high degree. I
10 usually find out -- I'm educated on stuff
11 before a sales rep is probably aware of
12 it.

13 And, of course, I don't --
14 I'm not at liberty to discuss that with
15 sales reps.

16 **Q.** What -- what are you not at
17 liberty to discuss with sales reps?

18 **A.** Well, for example, if I'm
19 involved in the -- if I've been consulted
20 upon the design of a new product, you
21 know, sales reps are not well versed or
22 maybe not aware of what things are in
23 development.

24 I'm just saying that most of

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1 the times, I'm a bit further along in
2 that regard, and my -- you know, my -- I
3 don't rely upon that relationship for
4 that kind of information.

5 Q. What Ethicon products were
6 you involved in the design, as you've
7 been referring to?

8 A. Well, I was -- as I
9 mentioned earlier, I was consulted on the
10 original TVT Retropubic. I offered
11 opinions on the Obturator product at some
12 point in time, the TVT-Secur. I had
13 significant involvement in the design of
14 the TVT EXACT® product.

15 Q. And would these have all
16 been prior to the devices going to
17 market?

18 A. A combination. Not
19 necessarily the same for each product.

20 Q. But at least for the
21 original TVT, you were consulted before
22 the product was marketed, I believe you
23 said; is that correct?

24 A. I recall being a part of

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1 expert focus groups that discussed the
2 concept that would look at towards am
3 what was the utility, the market need,
4 the viability.

5 Because I'm an educator,
6 it's likely that I was asked questions
7 regarding about -- about that.

8 Q. So at least for the sling
9 products, you were involved in the design
10 of the original TVT, the TVT-O, TVT-Secur
11 and TVT EXACT®; is that correct?

12 A. I don't -- I don't know that
13 I would say design in those. I was
14 involved in the design for the TVT
15 EXACT®.

16 The TVT product was already
17 set to be launched, so, clearly, it had
18 already been designed. I'm just saying
19 that I had input and my opinion was
20 sought out prior to the product being
21 launched.

22 Q. For which of those products
23 were you actually paid by Ethicon to give
24 your opinions as to the devices?

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1 **A.** To the best of my knowledge,
2 I provided paid consultant services on
3 all those products.

4 **Q.** And what about Ethicon's
5 prolapse products, were you involved in
6 the design of any of those?

7 **A.** I mean, I had involvement in
8 many products, some of which never saw
9 the light of day, as well as the TVT
10 Prolift family of products.

11 **Q.** So the PROLIFT® Anterior?

12 **A.** Correct.

13 **Q.** PROLIFT® Posterior?

14 **A.** Correct.

15 **Q.** PROLIFT® Total?

16 **A.** Yes.

17 **Q.** Do you remember the names of
18 any of the other devices that you
19 consulted on?

20 **A.** I could probably dredge that
21 from my memory, yes.

22 **Q.** All right. I'll take it.

23 **A.** I believe there was a
24 product called the V-Tac product. I

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1 believe there was a product called
2 PROSIMATM product. Obviously, the
3 PROLIFT® +M was simply a modification of
4 the original PROLIFT® procedure.

5 There was a product that I
6 was the originator of the concept, the
7 proof of concept, the initial engineering
8 that had to do with a post anal sling for
9 treatment of a different pelvic floor
10 disorder known as anal incontinence.

11 Q. Did that product ever have a
12 name?

13 A. You know, it had a name in
14 development. The product never came to
15 market.

16 Q. What was the name in
17 development?

18 A. In development, we would
19 refer to that product as the Post-Anal
20 Sling Surgery or PAS.

21 Q. And to the best of your
22 recollection, were you a paid consultant
23 for your involvement in each of those
24 products as well?

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1 **A.** To the best of my knowledge,
2 yes.

3 **Q.** Are you the type of doctor
4 that likes to see data before using a
5 product?

6 MR. SNELL: Objection.
7 Vague.

8 THE WITNESS: I would
9 characterize myself as somebody
10 who puts a great deal of
11 importance on sound scientific
12 principles. Certainly, when
13 high-quality data is available, it
14 is given the weight that it
15 deserves.

16 At different -- you know,
17 the area of urogynecology has
18 evolved tremendously in the past
19 20 years. I was very fortunate to
20 be within this field at very
21 early -- at a very early phase.
22 So there are certainly procedures,
23 techniques, theories that I was
24 involved with very early on, and,

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1 obviously, data comes a little bit
2 later.

3 BY MS. THOMPSON:

4 Q. And you actually were part
5 of a study comparing the retropubic TVT
6 to TVT-Secur; is that correct?

7 A. That is correct.

8 Q. Before beginning that study,
9 did you have any data on the TVT-Secur?

10 A. Yes.

11 Q. What was that data?

12 A. So there was the -- as is
13 typical, there are always safety and
14 efficacy studies that are put before --
15 I'm sorry, let me rephrase that.

16 There was preliminary
17 published data, I believe, from the UK or
18 Europe about the initial design and
19 development for the TVT-Secur. And that
20 would have been some of the data that we
21 were considering.

22 The reason for doing the
23 trial, of course, is that we already had
24 a procedure that was widely practiced and

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1 widely accepted that had a tremendous
2 amount of data supporting its long-term
3 safety and effectiveness.

4 And with a new product
5 available, we want to specifically
6 compare apples to apples.

7 Q. So it's your position that
8 there was published literature on the
9 safety and efficacy of the TVT-Secur
10 before it was launched in the U.S.?

11 A. I don't believe that's what
12 I said.

13 Q. Okay. Was there safety and
14 efficacy -- published safety and efficacy
15 studies on the TVT-Secur before it was
16 launched in the U.S.?

17 A. I don't have independent
18 recollection, as I sit here now, as far
19 as the timing of one versus the other.

20 Q. So you don't know, one way
21 or the other, whether there were any
22 published data on the TVT-Secur --

23 A. I'm not saying --

24 Q. -- before it was launched?

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1 **A.** I'm not saying that I don't
2 know. I'm just saying that as I sit here
3 in conversing with you now, I cannot, in
4 my mind, say, okay, the TVT-Secur was
5 launched on this particular date and the
6 safety -- excuse me, a clinical trial was
7 published before or after.

8 **Q.** What did you tell the
9 patients that enrolled in that study
10 about the safety and effectiveness of the
11 TVT-Secur?

12 **A.** Well, I mean, the patients
13 underwent standardized and uniform
14 informed consent that was the same across
15 the entire -- the entire study. This
16 consent was, of course, approved -- at
17 our -- at our institution it was approved
18 by our own internal -- our IRB.

19 As far as the exact language
20 of that, I can't tell you. But, you
21 know, essentially, we would explain to a
22 patient that there was an established
23 procedure that was widely practiced and
24 was an accepted first-line therapy for

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1 stress incontinence and that there was a
2 newer procedure that was FDA approved and
3 that it was our interest in comparing the
4 two products, looking at safety,
5 effectiveness, differences in recovery,
6 everything from activity, the amount of
7 pain medication someone was to take,
8 because we wanted to be able to
9 independently compare the two procedures
10 side by side in a scientific manner that
11 would attempt to minimize bias.

12 Q. Did you tell patients that
13 the TVT-Secur had never been used in a
14 woman, prior to launching?

15 MR. SNELL: Objection.
16 Foundation.

17 THE WITNESS: I don't
18 recall. I don't recall that I --
19 that I said that, no.

20 BY MS. THOMPSON:

21 Q. Was the TVT-Secur FDA
22 approved?

23 A. Yes. To the best of my
24 knowledge, the TVT-Secur was FDA

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1 approved.

2 Q. I want to go back to your
3 relationship with the Ethicon sales reps.

4 Do you recall who the sales
5 rep was that called on you here in
6 Philadelphia when you first began using
7 the TVT?

8 A. There were several. I don't
9 know who came first.

10 Q. Do you remember any of the
11 sales reps that have called on you here
12 in Philadelphia for Ethicon?

13 A. Yes.

14 Q. Which ones?

15 A. There was a woman, Eileen
16 Ghenn. There was --

17 Q. I'm sorry, how do you
18 spell Ghenn?

19 A. Ghenn? G-H-E-N-N, and
20 that's a guess.

21 I believe there was a
22 Marty -- I can't remember his last name.
23 There was another gentleman whose first
24 name was Tom. There was a woman by the

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1 name of Kathleen Feeney. There was, more
2 recently, a gentleman whose name escapes
3 me.

4 There were -- there were
5 half a dozen or more. I'm sorry.

6 Q. And of the ones that you
7 remember their names, can you tell me,
8 for example, Ms. Ghenn, when did she call
9 on you for Ethicon?

10 A. I honestly couldn't tell you
11 the dates.

12 Q. Is she still an Ethicon
13 sales rep and still calling on you?

14 A. No.

15 Q. And how about Marty, do you
16 recall the time frame where he called on
17 you as an Ethicon sales rep?

18 A. He was in -- he would have
19 been in the beginning. I can't tell you
20 that he was 1999, 2000, 2001. My
21 recollection was within the first three
22 or four years, I seemed to have a
23 different rep every year.

24 There's another woman by the

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1 name of Kathy, I believe.

2 I'm sorry.

3 Q. That's okay.

4 And Tom, do you remember
5 when Tom was a sales rep?

6 A. Counselor, I'm sorry, let
7 me -- I can't give you specifics on any
8 of these people.

9 Q. And that's fine. It's fine
10 to say --

11 A. Right. I don't recall.

12 Q. -- I don't recall, no, or I
13 don't remember.

14 And how about Ms. Feeney, do
15 you remember when she was a sales rep?

16 A. To the best of my
17 recollection, Ms. Feeney was my rep for
18 the longest period of time. Time frame
19 wise, it would -- I would be guessing. I
20 would say 2005 to 2009, for example. It
21 might have been a period of two to four
22 years. I honestly don't know.

23 Q. How about currently, is
24 there a sales rep that you're familiar

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1 with?

2 A. No, there is not.

3 Q. And Ms. Feeney is no longer
4 working for Ethicon; is that correct?

5 A. That's correct.

6 Q. And Kathy, do you remember
7 when Kathy --

8 A. No.

9 Q. -- was a sales rep?
10 Generally, did you have a
11 good relationship with the sales --
12 Ethicon sales reps, including the ones
13 that you mentioned?

14 A. Some better than others.

15 Q. Which ones were they better
16 with?

17 A. Again, these are transient
18 people in my life. I mean, Kathleen
19 Feeney and I had a reasonable
20 relationship. Eileen Ghenn and I, not so
21 much, that I recall.

22 I mean, there's really
23 nothing of any great meaning to these
24 relationships either way.

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1 **Q.** Did you have loyalty to the
2 sales reps?

3 **A.** No, not at all.

4 MR. SNELL: If you're going
5 to move to a different topic, can
6 we take a break?

7 MS. THOMPSON: Yeah, this is
8 a good time for a break.

9 MR. SNELL: We've been going
10 about an hour and-a-half.

11 MS. THOMPSON: Yes.

12 VIDEO TECHNICIAN: We are
13 off the record. The time is 2:41
14 p.m.

15 - - -

16 (Whereupon, a brief recess
17 was taken.)

18 - - -

19 VIDEO TECHNICIAN: This
20 marks the beginning of Video
21 Number 2. We are back on the
22 record. The time is 3:00 p.m.

23 BY MS. THOMPSON:

24 **Q.** Dr. Toggia, I do have a few

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1 more questions about sales reps.

2 A. Yes.

3 Q. How did you typically
4 contact the sales rep?

5 A. I would say most frequently
6 they came to my office, and we would have
7 a face-to-face discussion. I'm sure that
8 we had e-mail contact. There was
9 probably cell phone contact with some,
10 when cell phones were, you know, in
11 existence and sort of widely used to for
12 that reason.

13 Q. Did you ever use sales reps'
14 personal e-mails?

15 A. I used whatever e-mails they
16 gave me. So, yes, I'm -- it's -- if
17 they -- maybe if they e-mailed me from
18 their personal e-mail, my reply would
19 simply be back to them. I can't tell you
20 that I would distinguish between the two.

21 Q. And what about personal cell
22 phone numbers?

23 A. I honestly can't tell you
24 whether they had company cell phones,

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1 personal cell phones. I gave -- again,
2 whatever contact information might have
3 been presented to me on a business card,
4 I would -- I would assume -- I mean, I
5 was assuming I was calling a business
6 cell.

7 **Q.** Did you consider your
8 relationship with the sales rep
9 professional?

10 **A.** Yes.

11 **Q.** Was the relationship always
12 appropriate with the sales reps, in your
13 opinion?

14 **A.** Yes.

15 - - -

16 (Whereupon, Exhibit
17 Toggia-4, 3/19/09 E-mail from
18 Marc Toggia to Kathleen Feeney;
19 Subject: Re: These events were
20 approved 3.25 proctorship and 4.21
21 preceptorship, was marked for
22 identification.)

23 - - -

24 BY MS. THOMPSON:

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1 **Q.** I'm going to hand you
2 Exhibit Number 4. I'll give you a minute
3 to look at that.

4 **A.** Okay.

5 MR. SNELL: What number are
6 we on?

7 MS. THOMPSON: 4.

8 BY MS. THOMPSON:

9 **Q.** Can you describe this e-mail
10 chain with Kathleen Feeney, one of the
11 sales reps that you told us about
12 earlier?

13 **A.** Uh-huh. I don't -- I can't
14 tell you that I have -- it seems to me
15 like there is a variety of different
16 things being discussed over here.

17 **Q.** What were the dates of these
18 e-mails?

19 **A.** 2009.

20 **Q.** March of 2009?

21 **A.** Yes.

22 **Q.** Beginning at the bottom of
23 the first page?

24 **A.** Yes.

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1 **Q.** Could you just read what is
2 contained in these e-mails between you
3 and Ms. Feeney?

4 **A.** I'm -- she says, I am so --
5 and then she uses a word that I'm just
6 not going to mention out loud -- He's
7 nowhere from being done and wants no
8 help.

9 I think she's referring to
10 another surgeon that she was probably in
11 a case with. I mean, there's just no
12 context here. I'm sorry.

13 **Q.** Well, this e-mail is from
14 you.

15 **A.** I'm sorry?

16 **Q.** This e-mail is from you on
17 Thursday, March 19th, 10:46.

18 **A.** Okay.

19 I don't know -- I don't know
20 what -- I mean, it sounds like I was -- I
21 was scrubbed in with somebody else. I
22 honestly couldn't tell you what this --
23 what the context of that was.

24 **Q.** So would you read that

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1 again, knowing that that's you writing
2 the e-mail.

3 A. Yes. So, apparently, this
4 says, I am so f'ed, he's nowhere being
5 done and wants no help. You and I will
6 be having a lunch before my case.

7 Q. So you're comfortable
8 putting that word in an e-mail to the
9 sales rep, although you're not
10 comfortable stating the word here in this
11 deposition; is that correct?

12 A. That is correct.

13 MR. SNELL: Objection.

14 Argumentative.

15 Go ahead.

16 BY MS. THOMPSON:

17 Q. Okay. Go ahead and read the
18 next e-mail up.

19 A. Call me. Pulling up now.
20 Do you want to meet me outside in front?

21 Q. That's from Ms. Feeney to
22 you?

23 A. Yes.

24 Q. And then the next one?

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1 **A.** Still have not started.

2 **Q.** And then the one after that,
3 from Ms. Feeney?

4 **A.** Can you do her downstairs?

5 **Q.** And then the last one from
6 you to Ms. Feeney?

7 **A.** On top?

8 **Q.** Yes.

9 **A.** The first one?

10 **Q.** Yes.

11 **A.** No, maybe, though. Your
12 girlfriend Christine is here and won't
13 leave. I think she liked her last
14 suggestion too much.

15 **Q.** I don't think you read the
16 first sentence correctly.

17 MR. SNELL: I'm going to
18 object. He did read it.

19 MS. THOMPSON: Could you --
20 no. He read, no, maybe, though,
21 your girlfriend Christine.

22 And it actually reads, the
23 response to, Can you do her
24 downstairs, is, No, maybe you,

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1 though.

2 BY MS. THOMPSON:

3 **Q.** Am I reading that correctly?

4 **A.** I don't think so. I don't
5 know -- no. I don't -- I don't
6 appreciate what you're implying. And I
7 can tell you for sure that this has
8 nothing to do with -- with that.

9 **Q.** Well, tell -- give me
10 another explanation for why it would be
11 No, maybe you, though, in response to,
12 Can you do her downstairs?

13 **A.** Well --

14 MR. SNELL: Objection.
15 Argumentative.

16 THE WITNESS: -- "do her"
17 has nothing to do -- has nothing
18 to do with sex, I can guarantee
19 you that, on any level.

20 BY MS. THOMPSON:

21 **Q.** All right. Provide me the
22 alternative explanation.

23 **A.** I don't have the context of
24 what this is.

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1 **Q.** Well, these are your e-mails
2 with Ms. Feeney.

3 What context do you need?

4 **A.** I don't know what she's -- I
5 don't know what -- I mean, obviously,
6 there was a -- there's a conversation
7 going on that is not captured in the bulk
8 of this -- of this discussion.

9 I mean, there's hours and
10 hours that go -- they may not even be
11 related. I mean, there's hours that are
12 between the two.

13 **Q.** Was there other
14 correspondence during that hours -- those
15 hours?

16 **A.** I would have no idea.

17 **Q.** And who is Christine?

18 **A.** I think it's another -- I
19 think it's a sales rep for -- like, a
20 pharmaceutical sales rep or a different
21 sales rep. I have no idea who it is.

22 **Q.** Do you think these e-mails
23 with Ms. Feeney are appropriate?

24 **A.** I can't tell you that I

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1 recall -- I don't know the context. And
2 I don't know that these are related. And
3 I don't think that they're strung in the
4 manner that you're insinuating.

5 Q. Do you think these e-mails
6 are professional?

7 A. I don't think, in this line
8 of conversation, we were discussing
9 anything related to her -- to anything
10 that -- I don't know. I don't know what
11 these were referring to, to be honest
12 with you.

13 Q. Did you have any personal
14 phone calls with Ms. Feeney?

15 A. Yes. I mean, I'm sure that
16 I spoke with Ms. Feeney on a variety of
17 things. She may have told me things
18 about her kids, she may have had ideas
19 about job opportunities that she was
20 interviewing for. I'm sure she asked me
21 about friends, in terms of their health
22 or, you know, she had a sick grandmother
23 or something.

24 I mean, you know, people

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1 will -- as a physician, people will ask
2 you, you know, personal questions. And,
3 certainly, as a gynecologist, I suspect
4 that I'm probably asked more personal
5 questions, you know.

6 Q. Why did you misread that
7 sentence when I asked you to read it?

8 A. Counselor, I did not misread
9 that.

10 MR. SNELL: Objection. Hold
11 on. Hold on. That's
12 argumentative.

13 MS. THOMPSON: I'm just
14 curious --

15 MR. SNELL: That's
16 argumentative.

17 MS. THOMPSON: -- about a
18 question.

19 MR. SNELL: That's
20 argumentative.

21 THE WITNESS: To the best --

22 MR. SNELL: And your -- he's
23 already told your insinuation is
24 not whole --

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1 THE WITNESS: Right. And I
2 don't appreciate it either.

3 MR. SNELL: If you're here
4 to ask him about his opinions, why
5 don't you do that? Unless you're
6 trying to, like, just be totally
7 argumentative --

8 MS. THOMPSON: And I
9 didn't --

10 MR. SNELL: -- that's what
11 you're doing.

12 MS. THOMPSON: -- insinuate
13 anything --

14 MR. SNELL: Yes, you did.

15 MS. THOMPSON: -- or even
16 mention sex. He did.

17 MR. SNELL: Yes, you did.

18 MS. THOMPSON: Did I
19 anything about sex? I wanted him
20 to read the sentence, and he left
21 out -- it's the only thing he's
22 misread today. I was just curious
23 if he knew why he did that.

24 MR. SNELL: To the best of

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1 my knowledge, I read that sentence
2 exactly.

3 BY MS. THOMPSON:

4 Q. Well, you know that you did
5 not read it exactly, right?

6 MR. SNELL: Objection.

7 BY MS. THOMPSON:

8 Q. Because we read it back to
9 you from the transcript.

10 MR. SNELL: Argumentative.

11 THE WITNESS: Counselor, let
12 me state this clearly. I read
13 that sentence exactly. Maybe you
14 did not hear me read that exactly.

15 MS. THOMPSON: Okay. I can
16 pursue that.

17 Court reporter, could you
18 please read back Dr. Toggia's
19 answer when I asked the question
20 to read the e-mail from himself to
21 Ms. Feeney at the top of the page?

22 MR. SNELL: I'm going to
23 object. This is all asked and
24 answered and covered. I'm sorry.

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1 MS. THOMPSON: Are you going
2 to instruct him not to answer? He
3 said he --

4 MR. SNELL: I'm not
5 instructing him not to answer.
6 He's told you three times.

7 MS. THOMPSON: Then he can
8 answer my question that I just
9 asked.

10 Amanda, if you could go
11 ahead and read the question and
12 answer, please.

13 - - -

14 (Whereupon, the court
15 reporter read the following part
16 of the record:

17 "Question: And then the
18 last one from you to Ms. Feeney?

19 "Answer: On top?

20 "Question: Yes.

21 "Answer: The first one?

22 "Question: Yes.

23 "Answer: No, maybe, though.

24 Your girlfriend Christine is here

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1 and won't leave. I think she
2 liked your last suggestion too
3 much.")

4 - - -

5 BY MS. THOMPSON:

6 **Q.** Is it still your position
7 that you read that sentence -- that
8 e-mail correctly?

9 **A.** To the best of my knowledge,
10 I think I answered that.

11 **Q.** Okay.

12 **A.** Again, I would point out
13 that there is -- one of these -- the
14 initial one is 13:24 and the one above it
15 is 19:19.

16 **Q.** Okay. You answered my
17 question.

18 - - -

19 (Whereupon, Exhibit
20 Toggia-5, 10/23/08 E-mail from
21 Kathleen Toggia to Cindy
22 Pypcznski; Subject: FDA Toggia,
23 was marked for identification.)

24 - - -

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1 BY MS. THOMPSON:

2 Q. I'm going to hand you
3 another e-mail, also with Ms. Feeney.

4 Can you identify this
5 e-mail?

6 A. This appears to be an e-mail
7 from Kathleen Feeney to Cindy Pypcznski.

8 Q. Would you go ahead and read
9 that, please?

10 A. Cin, notice the totally
11 different tone. Also note the timing of
12 this e-mail after I had it out with him
13 on the phone. Not regarding this, of
14 course, as you saw. Again, please don't
15 share this with anyone, as he is a great
16 guy, friend and surgeon.

17 Q. Who is she referring to when
18 she states that she had it out with him
19 on the phone?

20 A. I don't know.

21 Q. But it follows an e-mail
22 that you sent to her, correct?

23 A. I don't know if there was
24 anything in between. Again, the

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1 difference in times is dramatic.

2 Q. My question is just this
3 was --

4 A. It's a different date, as a
5 matter of fact.

6 Q. This was provided to us as
7 an e-mail chain.

8 So it does follow an e-mail
9 that you sent to Ms. Feeney, correct?

10 A. I don't know.

11 Q. Would you please read --
12 what's the subject of the e-mail from Ms.
13 Feeney to Cindy?

14 A. It says, FDA, Toggia.

15 Q. Now, if you would look at
16 the e-mail from you to Ms. Feeney, and
17 the subject is, Stuff.

18 A. Correct.

19 Q. And it discusses the FDA,
20 correct?

21 A. Yes.

22 Q. And this e-mail was provided
23 as an e-mail chain.

24 Would it be a reasonable

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1 assumption to make that it was referring
2 to your e-mail below?

3 MR. SNELL: Objection.

4 Calls for speculation. Lacks
5 foundation. Calls for a
6 state-of-mind opinion.

7 MS. THOMPSON: Are you
8 suggesting that Ethicon produced
9 two unrelated e-mails on the
10 same --

11 MR. SNELL: No. You're
12 asking him to speculate about what
13 Kathleen Feeney did, sending
14 something to somebody else with a
15 different subject line, a whole
16 different day later, and you're
17 asking him to speculate that one
18 is connected to the other; when
19 he's already testified, asked and
20 answered, that he can't make that
21 connection.

22 MS. THOMPSON: Okay.

23 BY MS. THOMPSON:

24 Q. So you sent an e-mail to Ms.

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1 Feeney that was --

2 MS. THOMPSON: And please
3 object to form only.

4 BY MS. THOMPSON:

5 Q. You sent an e-mail to Ms.
6 Feeney that was -- that concerned the
7 FDA, and Ethicon has produced an e-mail
8 that is in the same e-mail chain that's
9 from Ms. Feeney to Cindy, that's
10 entitled -- it's titled, FDA Toggia.

11 And she says, Also note the
12 timing of this e-mail after I had it out
13 with him on the phone. Not regarding
14 this, of course, as you saw. Again,
15 please don't share with anyone, as he is
16 a great guy friend and surgeon.

17 Why don't you go ahead and
18 read the e-mail that you sent to Ms.
19 Feeney?

20 MR. SNELL: I'm going to
21 object. And move to strike what
22 she just did. There's not even a
23 question there.

24 THE WITNESS: To the best of

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1 my knowledge, this has absolutely
2 nothing to do with TVT or --

3 BY MS. THOMPSON:

4 Q. I just asked you to read --
5 read --

6 A. -- or the design of TVT.

7 Q. Excuse me. Dr. Toglia, I
8 just asked you --

9 A. Yes.

10 Q. -- to read your e-mail from
11 you to Ms. Feeney.

12 MR. SNELL: You can read it.

13 THE WITNESS: Thanks for the
14 referral. Sorry you have had such
15 a tough week. You know I always
16 have your back. The FDA warning
17 is a big bummer, but I don't think
18 it will affect you much. We will
19 make some mild changes in how we
20 counsel folks. It would be good
21 if we could figure out how much of
22 this is apogee versus other stuff.
23 Could use it as a spin versus -- I
24 don't know what -- gurt, or as an

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1 excuse to do a few informal
2 dinners with key clients to help
3 diffuse. I do think there is some
4 room -- some -- there are some
5 folks who are at higher risk for
6 pain that it is best to avoid,
7 hence the small drop off in our
8 numbers. Hopefully, your company
9 will lower your projections. I
10 think I may blow off Chicago and
11 just relax.

12 BY MS. THOMPSON:

13 **Q.** What was the FDA warning
14 that you were referring to in this
15 e-mail?

16 **A.** Well, it's dated 2008, so I
17 am -- I am guessing, and it would be a
18 pure guess that it was an FDA warning --
19 the first FDA safety letter that spoke
20 about vaginal mesh kits.

21 **Q.** And in this e-mail, you felt
22 that some mild changes in how you
23 counseled folks would be the way to
24 address that FDA warning?

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1 **A.** No. Because we were already
2 addressing the FDA warning, the mild
3 change was the fact that we would include
4 the words, "the FDA has issued."

5 But we had always been, with
6 these kits, very up front with our
7 patients and would say, this is a newer
8 procedure, it represents only one --
9 basically, everything that the FDA stated
10 in there, we were independently doing
11 prior to the FDA's recommendations.

12 The minor change would have
13 been that we would now say that there was
14 an FDA and we were provided that
15 reference.

16 **Q.** Okay. And then you mention
17 that there are some folks at higher risk
18 for pain that's best to avoid.

19 Did Ethicon ever tell you
20 that there were patients who would be
21 high risk for pain that you should avoid
22 the use of mesh kits?

23 **A.** I would not rely upon
24 Ethicon to tell me that kind of stuff.

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1 We were -- as we sort of
2 developed through the procedure, we
3 both -- we both -- we both became more
4 aware of groups of patients in whom the
5 product was appropriate, groups of
6 patients in whom we thought the procedure
7 was not ideal.

8 And we -- you know, all
9 surgical procedures have elemental
10 risks --

11 **Q.** Excuse me, if you can just
12 ask my -- answer my question, we'll move
13 along a lot faster.

14 **A.** I'm sorry?

15 **Q.** The question was, did
16 Ethicon tell you that there were patients
17 at high risk for pain that should not use
18 the kits?

19 **A.** No.

20 **Q.** Thanks.

21 Do you know when Ms. Feeney
22 left Ethicon?

23 **A.** I don't know. 2009. I'm
24 just guessing. 2011. I don't know.

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1 **Q.** Was she fired?

2 **A.** I was never told the reason
3 why she stopped working for the company.

4 **Q.** If I told you it was in
5 2009, would you have any reason to
6 disagree with that?

7 MR. SNELL: Objection.
8 Foundation.

9 THE WITNESS: No.

10 BY MS. THOMPSON:

11 **Q.** I'll give you another e-mail
12 with Ms. Feeney.

13 - - -

14 (Whereupon, Exhibit
15 Toggia-6, 4/27/09 E-mail from
16 Marc Toggia to Kathleen Feeney;
17 Subject: RE: Itinerary for TVT
18 Proctorship, was marked for
19 identification.)

20 - - -

21 MR. SNELL: Is this 6?

22 MS. THOMPSON: I believe so.

23 THE WITNESS: Yes.

24 BY MS. THOMPSON:

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1 **Q.** Would you just read the top
2 e-mail that's from you to Ms. Feeney in
3 April of 2009?

4 **A.** I found the name for 5/28.
5 It is Finkelstein. Sorry for this. I
6 know it seems unimportant. I guess I'm
7 just trying to keep myself distracted.
8 Good luck. Regardless of what happens,
9 you know that I think you're the best and
10 have no questions regarding your moral
11 integrity. Please call me afterwards.

12 **Q.** Can you tell us about the
13 context of this e-mail?

14 **A.** I honestly have no idea what
15 any of this refers to.

16 **Q.** So you sent Ms. Feeney an
17 e-mail about not having questions about
18 her moral integrity, but you can't
19 remember what that could have referred
20 to?

21 **A.** It's dated in 2009. She may
22 have left the company, was leaving the
23 company, was concerned she was leaving
24 the company. I was just offering some --

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1 some support.

2 Q. But you don't remember
3 anything --

4 A. I mean --

5 Q. -- more than that?

6 A. She could have -- she could
7 have questioned herself or said -- you
8 know, this may not have even been work
9 related. She could have been having
10 problems at home, and I was just trying
11 to -- to reassure her.

12 I honestly don't. I
13 honestly don't. I don't know who
14 Finkelstein is. I don't know what the
15 name applies to. I don't know what any
16 of this is in the context of, I'm sorry.

17 MS. THOMPSON: We'll request
18 any e-mails between you and Ms.
19 Feeney on her personal e-mail.

20 BY MS. THOMPSON:

21 Q. And if Ms. Feeney gives an
22 explanation for this e-mail, would you
23 have any reason to -- or basis to
24 disagree with her interpretation?

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1 MR. SNELL: Objection. Hold
2 on. Calls for speculation. Lacks
3 foundation.

4 MS. THOMPSON: Form is fine.

5 MR. SNELL: No, but I'm
6 articulating the form, that's what
7 it is. There's no problem with
8 that.

9 MS. THOMPSON: I don't
10 believe -- I don't think that's
11 the case.

12 Yes.

13 BY MS. THOMPSON:

14 Q. Would you have any reason to
15 disagree?

16 A. I -- I might. I don't -- I
17 honestly don't know what -- what we were
18 referring to here. These are -- these
19 are random snippets, you know. There's
20 no context.

21 Q. Well, if -- if you don't
22 recall, then you would not be able --
23 have any basis to disagree with her
24 recollection, then?

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1 MR. SNELL: Objection.

2 Calls for speculation.

3 THE WITNESS: It's possible
4 that her recollection may give me
5 further information. I don't
6 know.

7 BY MS. THOMPSON:

8 Q. When you began using the TVT
9 in 1999, what did you provide patients,
10 when you were getting informed consent
11 for the use of the product, regarding
12 risks?

13 A. So we were very -- I was
14 very clear with my patients, at the time,
15 what the traditional therapies, surgeries
16 were, what the elemental risks were, the
17 fact that -- that in the previous ten
18 years there was a paradigm shift in the
19 understanding of what caused stress
20 incontinence, how stress incontinence
21 might be treated differently --

22 Q. Dr. Toggia, I'm sorry to
23 interrupt, but I'm just asking you what
24 you told patients about the risks

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1 associated with TVT?

2 **A.** I'm telling you.

3 MR. SNELL: Objection. He's
4 being responsive.

5 THE WITNESS: I'm telling
6 you what that -- what that answer
7 is.

8 BY MS. THOMPSON:

9 **Q.** If that's responsive, okay.

10 **A.** Okay. So in that context,
11 we would have gone over the current --
12 the current available choices, we would
13 talk, of course, first, about what was
14 established and what was commonplace and,
15 certainly, what my experience had been.

16 We would talk about the
17 newer procedure, the preliminary
18 experience, the theoretical benefits that
19 might come from the newer procedure.

20 And I would have been very
21 specific with them, as far as what my
22 specific experience was, i.e., this is
23 the third one I've done, this is the
24 fifth one I've done.

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1 And also within that
2 context, we would have said, thus far in
3 this experience, we have seen the
4 following outcomes.

5 Q. What risks did you tell the
6 patient were associated with the TVT --

7 A. Sure. I'm sorry.

8 Q. -- device when you counseled
9 her?

10 A. Sure. It's the same
11 elemental risks. We would have talked
12 about the risks of voiding dysfunction,
13 the risk of possible injury to the
14 vagina, to the bladder, to blood vessels
15 or nerves. The theoretical risk as it
16 relates to infection. Any risk that
17 might be unique to the placement of -- of
18 mesh material.

19 It's the same -- it's the
20 same discussion that we had with all of
21 the procedures that we do.

22 Q. What were the risks that you
23 would have told your patient that are
24 unique to the mesh material?

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1 **A.** In all honesty, and I'm not
2 trying to be difficult, I can't tell you
3 that the risks are unique. They all
4 carry a risk of bladder injury. They all
5 carry a risk of urethral injury.

6 Autologous fascial slings
7 can erode, can have wound disruptions,
8 which is a similar risk that, say, a
9 midurethral sling could have.

10 **Q.** So is it your opinion that
11 there are no risks that are unique to the
12 mesh material contained in the TVT
13 device?

14 **A.** I mean, obviously, exposure
15 of synthetic mesh material, you know, as
16 opposed to exposure of permanent suture
17 material with the Burch, per se, as
18 opposed to, say, exposure of the fascial
19 slings.

20 **Q.** So the exposure is the same
21 in all three procedures, it's just the
22 material that's being exposed is the only
23 difference that you can identify?

24 **A.** Say that again, please.

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1 **Q.** Is it only the difference in
2 the material that is exposed in the
3 vagina, not the actual fact that TVT can
4 become exposed in the vagina?

5 **A.** Well, I think -- I think,
6 you know, again, it's -- what we always
7 do is we will compare one procedure to
8 the next procedure.

9 So, for example, you know, a
10 Burch procedure is done with a
11 laparotomy, okay? There are certain
12 risks that are more common with a
13 laparotomy, wound infection, wound
14 breakdown, bleeding.

15 There may be other risks
16 that are a little less common with that
17 Burch procedure.

18 At the time I would say,
19 probably bladder injury was a risk that
20 we -- in our experience, was maybe a
21 little less common, although I think
22 Level 1 evidence really suggests that all
23 the risks are within in the same
24 ballpark.

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1 **Q.** Do you get exposure of
2 permanent suture in the vagina with a
3 Burch procedure?

4 **A.** Yes. It's actually one of
5 the more common things that we see.

6 **Q.** Do you get bladder erosion
7 with a Burch procedure?

8 **A.** Yes. It's one of the more
9 common things that we see.

10 **Q.** How common are bladder
11 erosions with a Burch?

12 **A.** Can I refer to one of the
13 systematic review studies?

14 **Q.** Sure.

15 **A.** So I was hoping to find a
16 more specific -- specific number to give
17 you, but I would say, in general, it's
18 probably in the 3 to 4 percent range that
19 we would see a PROLENE® suture erode into
20 the bladder.

21 **Q.** Are PROLENE® sutures used
22 commonly for Burch procedures?

23 **A.** Permanent sutures are used
24 commonly --

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1 Q. My question is --

2 A. -- for Burch procedures.

3 Q. -- are PROLENE® suture used
4 commonly for Burch procedures?

5 A. PROLENE® sutures is -- is a
6 common choice of a suture for it, yes.

7 Q. Is that what you use if
8 you're doing a Burch procedure?

9 A. We would either use PROLENE®
10 or we would use ETHIBOND. We probably
11 use them equally.

12 Q. And while you're at it, why
13 don't you look for the incidence of
14 vaginal exposure of suture with a Burch
15 procedure?

16 A. To answer that question, I
17 think I have to refer to my expert
18 report.

19 Q. While you're doing that, how
20 about urethral exposure --

21 A. Counselor, I'm sorry --

22 Q. -- with a Burch procedure.

23 A. -- being your typical male,
24 I don't multitask very well. However, I

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1 guarantee you --

2 **Q.** All right. I will wait.

3 **A.** -- I can do two serial tasks
4 very, very, quickly.

5 **Q.** Okay. I'm just trying to
6 get you out of here earlier.

7 **A.** Counselor, I am -- I am at
8 your disposal. I'm here as long as you
9 would like me to be here.

10 **Q.** All right. That's great to
11 hear.

12 MR. SNELL: She gets seven
13 hours on the record.

14 THE WITNESS: You've got six
15 hours, 15 minutes left.

16 Can you read me back the
17 question again, please?

18 - - -

19 (Whereupon, the court
20 reporter read the following part
21 of the record:

22 "Question: And while you're
23 at it, why don't you look for the
24 incidence of vaginal exposure of

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1 suture with a Burch procedure?")

2 - - -

3 THE WITNESS: I recall that
4 there was one trial where, I
5 believe, approximately 5
6 percent -- I might have to find
7 the Novara study.

8 MS. THOMPSON: Let's just go
9 off the record, Greg, if you don't
10 mind, while he looks for the
11 studies.

12 VIDEO TECHNICIAN: We are
13 off the record. The time is 3:32
14 p.m.

15 - - -

16 (Whereupon, a discussion off
17 the record occurred.)

18 - - -

19 VIDEO TECHNICIAN: We are
20 back on the video record. The
21 time is 3:41 p.m.

22 THE WITNESS: Thank you. I
23 apologize it's taking me so long.

24 So the first study that I

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1 want to reference with regard to
2 the question of the suture erosion
3 to the bladder is going to be the
4 Cochrane review. This would be
5 the Lapitan and Cody study, 2012
6 Cochrane review.

7 Data from -- and they're
8 referencing the Albo trial.

9 Data from this trial showed
10 a fivefold higher risk of having
11 sutures pass through the bladder
12 with open colposuspension compared
13 to doing a pubovaginal sling
14 procedure; perforation rate, 3
15 percent.

16 And if you'd like to go off
17 the record again, I'm happy to
18 find the second paper.

19 BY MS. THOMPSON:

20 Q. That's talking about
21 intraoperative risk, correct, not
22 erosion?

23 Dr. Toggia --

24 A. Yes? I'm sorry.

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1 **Q.** -- the passage you just read
2 to me is talking about an intraoperative
3 risk of passing suture through the
4 bladder, correct?

5 **A.** Sutures passed through the
6 bladder during open colposuspension.

7 **Q.** That's not referring to
8 erosion into the bladder, is it?

9 **A.** No, it's not. I'm sorry.
10 So it wasn't suture -- it
11 wasn't suture exposure in the
12 bladder, was that -- was that not
13 the question?

14 **Q.** The question was bladder
15 erosion of suture with a Burch
16 colposuspension.

17 So you'll agree that the
18 sentence you just read doesn't have
19 anything to do with bladder erosion?

20 **A.** Counselor, I will agree that
21 the sentence I just read you talked about
22 the passage of suture into the bladder.

23 I'm sorry if I --

24 **Q.** And that's not erosion,

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1 correct?

2 **A.** I'm sorry if I misunderstood
3 your question.

4 MS. THOMPSON: I guess we'll
5 go off the record again.

6 THE WITNESS: Thank you.

7 VIDEO TECHNICIAN: We are
8 off the record. The time is 3:44
9 p.m.

10 - - -

11 (Whereupon, a discussion off
12 the record occurred.)

13 - - -

14 VIDEO TECHNICIAN: We are
15 back on the record.

16 THE WITNESS: Thank you. So
17 with regard to the question of the
18 rate of suture erosion into the
19 bladder, it's my general
20 recollection that there's about a
21 3 to 5 percent risk of suture
22 erosion with the traditional Burch
23 procedure when performed with
24 PROLENE® sutures.

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1 BY MS. THOMPSON:

2 Q. And what about the risk of
3 suture erosion into the vagina with a
4 Burch?

5 A. I would say it's probably in
6 the -- in the same ballpark.

7 Q. And what about suture
8 erosion into the urethra with a Burch?

9 A. That should really not
10 occur, because the Burch suspension is
11 not placed at the level of the urethra.

12 Q. And it's your testimony --
13 but, at least as you're sitting here
14 today, you can't give me a reference for
15 those numbers?

16 A. Yes.

17 Q. Yes, you cannot?

18 A. Yes, I cannot give you a
19 reference for those numbers. Yes.

20 Q. Thank you.

21 And is your testimony, then,
22 that there's really no complications that
23 are unique to the -- to a synthetic
24 midurethral sling?

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1 MR. SNELL: Objection.

2 Asked and answered.

3 THE WITNESS: Each procedure
4 has risks. The majority of those
5 risks, I would say are elemental,
6 are common to the group. However,
7 each procedures do have risks that
8 are more common, perhaps, and
9 possibly could be unique.

10 For example, with the
11 poly-tetrafluoride sling, there
12 was -- or the Ob Tape sling --

13 BY MS. THOMPSON:

14 Q. Let me clarify my question
15 and just limit it to synthetic
16 polypropylene slings.

17 A. Okay. Thank you.

18 So with -- with reference to
19 the TVT Type I polypropylene sling -- I'm
20 sorry, but I can't think of a risk that's
21 unique to that -- to that compared to the
22 other procedures that we do.

23 Q. And you'll agree with me
24 that, in terms of significance, the

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1 severity of a complication is important,
2 correct?

3 A. I'm not sure that I
4 understand your question.

5 Q. When you're considering
6 risks associated with a procedure, the
7 severity of that complication is
8 important to you as a physician, correct?

9 A. Can you tell me what you
10 mean by "severity"?

11 Q. Well, there are minor
12 complications and there are severe
13 complications, right?

14 A. But one person's minor
15 complication is a severe complication,
16 and vice versa.

17 Could you be --

18 Q. Well, there are actually
19 some definitions of the severity of
20 complications.

21 But you'll agree with me
22 that -- are you just really telling me --

23 A. No, counselor --

24 Q. -- that you don't understand

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1 what I mean by the severity of a
2 complication is important?

3 A. I'm just not sure of the
4 context.

5 So, first of all, I will
6 agree with you that there are less severe
7 complications and there are more severe
8 complications with each of these
9 anti-incontinence procedures.

10 Q. That was all I'm asking.

11 A. I'm sorry.

12 Q. And I wasn't even specific
13 to --

14 A. Okay.

15 Q. -- to a device.

16 I was just saying, there are
17 minor complications and severe
18 complications, right?

19 A. Yes.

20 Q. And that makes a difference
21 whether you're talking about a rate of
22 minor complications or you're rating --
23 talking about a rate of severe
24 complications?

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1 **A.** I'm sorry. I understand you
2 now.

3 **Q.** Okay.

4 **A.** Yes.

5 **Q.** All right.

6 **A.** So, for example, urinary
7 tract infection is oftentimes cited as a
8 complication. One can argue that a
9 urinary tract infection would be a less
10 severe type of a complication.

11 **Q.** But a urinary tract
12 infection with sepsis and intensive care
13 could be a serious complication?

14 **A.** That's a good point,
15 counselor.

16 **Q.** Thank you.

17 MR. SNELL: Can we take a
18 break whenever you get right a
19 stopping point? Because I need to
20 use the restroom.

21 MS. THOMPSON: Maybe five
22 minutes.

23 MR. SNELL: That's fine.

24 BY MS. THOMPSON:

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1 **Q.** Now, when we started this
2 line of questioning, it's been a while,
3 but I think we were talking about what
4 you told your patients in 1999 --

5 **A.** Yes.

6 **Q.** -- when you first started --

7 **A.** I'm sorry, yes.

8 **Q.** -- using the TVT.

9 I have a little bit
10 different question and that is now, in
11 2015, when you are using a retropubic TVT
12 device, are there any additional risks or
13 complications that you discuss with your
14 patients, as opposed to what you did in
15 the early years of using the device?

16 **A.** Well, now that I'm 17 years
17 into this experience and now that I've
18 done, let's say, well over 2,000 cases,
19 again, I like to talk to my patients
20 about things that might go wrong during
21 the procedure, things that possibly could
22 complicate their postoperative course,
23 things that might occur during the life
24 of that procedure.

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1 So to speak backwards, what
2 we typically tell our patients these days
3 is that, you know, over the ten-year
4 period, subsequent to, say, having a
5 midurethral sling -- and when I say
6 "midurethral sling," I am referring
7 specifically to the TVT, since that's
8 what I perform, there's about a 3
9 and-a-half percent risk of having to
10 return to the OR for something; that
11 might include failure, that could include
12 difficulty voiding, et cetera.

13 Overall, the risk that we
14 talk to people about, in our hands, are
15 sort of the risk of bladder injuries,
16 about 1 percent; our mesh exposure rate
17 is under 1 percent; our risk of voiding
18 dysfunction is well under 1 percent; our
19 rate of infection has been zero percent
20 over -- over the 17-year experience; the
21 rates of urethral injury, well under 1
22 percent.

23 And I make it a point of
24 saying, look, just because something

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1 occurs very infrequently, doesn't
2 necessarily mean that when it does occur
3 it's not a significant complication.

4 Q. Are synthetic sling
5 complications underreported in the
6 literature, in your opinion?

7 A. Absolutely not. Again, we
8 have -- we have more than 20 -- excuse
9 me, we have at least, you know, eight to
10 ten long-term registry studies that have
11 followed people for at least five years.
12 Some studies have gone out to ten years.
13 And these are high quality, high level of
14 evidence, of scientific papers.

15 And I would say, you know,
16 ballpark figure, long-term complications
17 are all sub 3 percent.

18 Q. How many deaths are reported
19 in the literature from the TVT retropubic
20 device?

21 A. And, again, I don't think
22 that you can derive incidence or
23 prevalence because, you know --

24 Q. I'm not asking for incidence

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1 or prevalence. I'm asking how many are
2 reported?

3 A. I don't know. I would -- I
4 would venture -- I don't know.

5 Q. Are you aware of any --

6 A. I --

7 Q. -- reported?

8 A. I'm aware of, I'm going to
9 say, five to seven deaths.

10 Q. Reported in the literature,
11 is my question?

12 A. Oh, reported in the
13 literature -- I don't know how many have
14 been reported in the literature.

15 Q. Are you aware of any deaths
16 reported in the literature from the TVT
17 device?

18 A. You know, when I --

19 Q. The question is, are you
20 aware of any?

21 A. I'm just trying to explain
22 to you, if I'm aware of five to seven I
23 wouldn't be --

24 Q. I'm not asking you how many

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1 you think have occurred --

2 **A.** Right.

3 **Q.** -- I'm asking you how many
4 have been reported in the literature?

5 **A.** In my reading of the
6 literature, I'm saying that I am aware of
7 about five to seven. I'm just saying
8 that I cannot produce to you what -- in
9 what form or publication they would have
10 been.

11 **Q.** And how many do you think
12 have actually occurred?

13 **A.** I don't know, counselor.

14 **Q.** So you think there are five
15 to seven deaths reported in the
16 literature from TVT?

17 **A.** That's the best of my
18 recollection. But I will tell you that
19 I'm not aware of any personally.

20 **Q.** Do you tell your patients
21 that polypropylene degrades in the human
22 body?

23 **A.** There is no high-quality
24 evidence that suggests that polypropylene

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1 degrades in the body.

2 **Q.** What does degradation mean
3 to you?

4 **A.** Well, again, and I looked
5 this up. It just -- it depends. And the
6 definition varies.

7 Degradation is -- to me,
8 means a loss of structural integrity, a
9 loss of function.

10 You can certainly degrade
11 one's morality, that's a different
12 mention, that's obviously not applicable
13 within the setting of the mesh.

14 **Q.** Okay. And it's your opinion
15 that there's no high-quality study that
16 shows -- that mesh degrades?

17 **A.** I'm quite certain that there
18 is no high-quality studies that would
19 suggest that the mesh degrades. It is
20 certainly inconsistent with the body of
21 Level 1 evidence and the long-term
22 registration studies.

23 **Q.** Is there high-quality
24 evidence, in your opinion, that states

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1 that mesh does not degrade?

2 A. Well, I don't know how we
3 would know that, counselor, because we
4 don't routinely explant mesh that is
5 behaving properly in the body.

6 Q. Does mesh that's not
7 behaving properly in the body degrade?

8 A. Again, I'm not aware of any
9 high-quality data. I can tell you
10 that -- the data is very, very clear and
11 very reassuring that there are no
12 clinical concerns that that phenomenon
13 exists.

14 Q. That's not my question. I'm
15 not talking clinically.

16 A. Yes.

17 Q. I'm talking about, and I
18 would --

19 A. Degrading in the body is a
20 clinically-based question.

21 Q. No. I'm talking about
22 degradation, not clinical.

23 A. Okay.

24 Q. But you mentioned the

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1 structural composition of the
2 polypropylene.

3 MR. SNELL: I'm going to
4 object. That misstates. He said
5 structural -- well, the record
6 will be clear what he said. And I
7 think he was responsive with
8 regard to how he defines
9 degradation.

10 BY MS. THOMPSON:

11 Q. Okay. I'm going to -- I'm
12 going to define degradation in the
13 chemical sense, and that is a change in
14 the chemical structure of the compound.

15 A. Okay.

16 Q. Are there any studies in the
17 literature that tell you that that does
18 not happen with the TVT mesh when placed
19 in a woman's body?

20 A. Can I ask you to restate
21 that without the double negative, please?

22 Q. Well, you told me there are
23 no high-quality studies that state that
24 it degrades. I don't know how to do that

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1 without the negative.

2 Are there any studies that
3 show you that it does not degrade?

4 **A.** The study by Falconer, which
5 I believe was published in 2001, where
6 they did, in fact, go back and take site
7 specific biopsies showed no degradation
8 in the material.

9 **Q.** Now, were they looking at
10 that from a chemical composition
11 standpoint?

12 **A.** Again, if you would like to
13 give me a minute to locate that study.

14 MS. THOMPSON: Okay. We'll
15 go off the record.

16 VIDEO TECHNICIAN: We are
17 off the record. The time is 3:58
18 p.m.

19 - - -

20 (Whereupon, a discussion off
21 the record occurred.)

22 - - -

23 VIDEO TECHNICIAN: We are
24 back on the video record.

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1 THE WITNESS: Read me the
2 question one more time, please?

3 - - -

4 (Whereupon, the court
5 reporter read the following part
6 of the record:

7 "Question: Now, were they
8 looking at that from a chemical
9 composition standpoint?")

10 - - -

11 THE WITNESS: So, no. The
12 Falconer study was looking at it
13 from a histologic standpoint. I'm
14 not aware of any concerns that
15 there might be degradation that
16 would prompt one to do those kinds
17 of studies.

18 BY MS. THOMPSON:

19 Q. And that study also was
20 biopsying the tissue around the mesh
21 product, not the mesh itself, correct?

22 A. You are correct, counselor.

23 Q. So you're not aware of any
24 studies, then, that demonstrates that

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1 polypropylene mesh does -- or TVT mesh
2 does not degrade in the female body?

3 MR. SNELL: Objection.

4 Asked and answered.

5 MS. THOMPSON: Well, he said
6 he would look and he found
7 Falconer, which doesn't apply, so
8 I'm asking if he has any others.

9 MR. SNELL: I'm going to
10 object. That's also vague. You
11 asked him specifically, in the
12 last question, about chemical
13 degradation. And now you said
14 degradation. He already said he
15 doesn't think degradation occurs,
16 and he's told you all the reasons
17 why.

18 MS. THOMPSON: All right.
19 Fair enough. I'll ask it -- I'll
20 ask again with chemical
21 degradation.

22 BY MS. THOMPSON:

23 Q. Are you aware of any
24 studies, then, that demonstrate that

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1 chemical degradation does not occur with
2 polypropylene mesh implanted in the body?

3 **A.** I think that the long-term
4 registry trials and the significant lack
5 of chronic problems suggests that there
6 is no chemical degradation of the
7 material.

8 I'm also -- I'm a little
9 bit -- what does it matter if the
10 material degrades if the person is still
11 continent? You know, it's not that
12 are -- we're suspending somebody from a
13 bridge from this material and that loss
14 of the material would compromise that
15 person's position.

16 The procedure is designed to
17 reestablish urethral stability, and it
18 does so effectively in studies that have
19 gone up to 17 years.

20 **Q.** So is it your opinion that
21 degradation -- chemical degradation of
22 the material doesn't matter if the woman
23 is still continent?

24 **A.** Well, and, again, I'm

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1 certainly not trying to be difficult, but
2 I'm not certain what you mean by
3 "chemical degradation," what
4 specifically, what we're looking at,
5 we're changing in, we're talking about
6 isomeric change in the compound? We're
7 talking about racemic change in the
8 compound? We're talking about
9 nephelation of the compound? What --
10 what specifically is implied with the
11 term "chemical degradation"?

12 Q. You're not a chemist, right?

13 A. I have a degree in
14 biochemistry. I have done chemical
15 research.

16 Q. But you don't consider
17 yourself a chemist?

18 MR. SNELL: Objection.

19 THE WITNESS: I think I just
20 told you what my --

21 BY MS. THOMPSON:

22 Q. So you are a chemist?

23 A. What's that? I --

24 Q. You do consider yourself an

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1 expert in chemistry?

2 A. Those are different
3 questions.

4 Q. Do you consider yourself an
5 expert in chemistry?

6 A. I would consider myself an
7 expert in chemistry, yes.

8 Q. And -- but you're not
9 familiar -- are you familiar with the
10 term "oxidation"?

11 A. Of course.

12 Q. Are you familiar with the
13 term "oxidative degradation"?

14 A. Yes.

15 Q. Let's just use oxidative
16 degradation, then, maybe we can --

17 A. Fair enough.

18 Q. -- get on the same page
19 here.

20 A. Sure.

21 Q. Are you aware of any studies
22 that show that oxidative degradation does
23 not occur with polypropylene mesh placed
24 in the body?

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1 **A.** There are no high-quality
2 evidence studies that suggest that it
3 does occur. Therefore, my inference
4 would be that it does not occur.

5 **Q.** What does oxidative
6 degradation mean to you?

7 **A.** Oxidative degradation is the
8 process in which oxygen comes in and will
9 alter the composition; so, you know,
10 you've got nitrous oxide it becomes
11 nitric oxide.

12 **Q.** What happens when
13 polypropylene undergoes oxidative
14 degradation?

15 MR. SNELL: Objection. It
16 lacks foundation. He's told you
17 he doesn't believe it does.

18 BY MS. THOMPSON:

19 **Q.** So is it your opinion that
20 polypropylene does not undergo oxidative
21 degradation in vitro or in vivo?

22 **A.** I'm speaking in vivo; I'm
23 not aware of any high-quality evidence
24 that would suggest that polypropylene

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1 mesh, within the context of the TVT
2 device and its intended use to treat
3 stress incontinence in women, which was
4 the subject that I was asked to research
5 and form an opinion, undergoes oxidative
6 degradation.

7 Q. Are you a materials expert?

8 A. I certainly am a materials
9 expert, yes. At least --

10 Q. Are you a polymer expert?

11 A. I have a better than
12 average, and some would consider to be an
13 expert understanding, of polymer medicine
14 as it relates to my subspecialty field,
15 yes.

16 Q. Is it your opinion -- well,
17 let me ask you this: What additives go
18 into the mesh that the TVT is comprised
19 of?

20 A. Can you be more specific?

21 Q. What additives are added to
22 the polypropylene resin that makes up the
23 TVT?

24 A. I mean, there's an enormous

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1 amount --

2 Q. If you don't know, it's
3 fine. Just say you don't know.

4 What additives go into the
5 mesh -- to the resin that forms the TVT
6 mesh?

7 A. I'm not sure I know what
8 you're referring to, in terms of adding
9 oxygen goes into it.

10 Q. Is the polypropylene that's
11 used in the TVT mesh pure polypropylene?

12 A. Well, no. Polypropylene
13 itself is not a pure molecule. I mean,
14 there are --

15 Q. What is added to the
16 polypropylene or is nothing added or do
17 you not know?

18 A. I can't tell you off the top
19 of my head all of the different compounds
20 that would go into the -- you know, the
21 creation and the extrusion of
22 polypropylene.

23 Q. Did you ever ask anyone at
24 Ethicon what was in the polypropylene?

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1 **A.** I did not ask anybody at
2 Ethicon what was in polypropylene.

3 But that shouldn't imply
4 that I did not read about polypropylene
5 mesh or the base PROLENE® material.
6 These are materials that we have used
7 extensively in the last 40 to 50 years in
8 the area of surgery.

9 **Q.** Did Ethicon tell you that
10 its own studies on PROLENE® suture shows
11 that it degrades?

12 MR. SNELL: Objection.
13 Misstates. Lacks foundation.

14 THE WITNESS: I would not
15 rely upon Ethicon to tell me such
16 things.

17 And, again, this is within
18 the context of the TVT design, I'm
19 not aware of -- you know, the
20 animal studies really are not
21 relevant. We have Level 1
22 evidence to support the long-term
23 safety of these things --

24 BY MS. THOMPSON:

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1 **Q.** I'm not talking about -- if
2 we can get away from the long-term
3 safety. I'm not discussing the long-term
4 safety. I'm discussing the material
5 itself.

6 **A.** Yes.

7 **Q.** If Ethicon has information
8 that the material degrades in the human
9 body, is that something that you, as a
10 doctor, would want to know about?

11 MR. SNELL: Objection.

12 Lacks foundation.

13 Go ahead.

14 THE WITNESS: I would not be
15 dependent upon Ethicon --

16 BY MS. THOMPSON:

17 **Q.** I didn't ask you --

18 **A.** -- for that information.

19 **Q.** -- if you depended on it.

20 Is that something that you
21 would like to know, if Ethicon has
22 information that their product degrades,
23 is that something you would want to know,
24 as a physician?

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1 MR. SNELL: Objection.

2 Lacks foundation. Misstates
3 evidence.

4 THE WITNESS: No, it is not.

5 BY MS. THOMPSON:

6 Q. It's not something that you
7 would want to know?

8 A. I would not want to know it
9 from Ethicon, no.

10 Q. Who would you know it from?

11 A. Would I know what from?

12 Q. Who is going to tell you
13 that Ethicon mesh degrades if it's not
14 Ethicon?

15 MR. SNELL: Objection.

16 Hypothetical. Calls for
17 speculation.

18 MS. THOMPSON: Well, he
19 brought it up. He didn't want to
20 hear it from Ethicon.

21 BY MS. THOMPSON:

22 Q. I'm asking you, who else
23 would you want to hear it from?

24 MR. SNELL: You asked him

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1 the question. He's already told
2 you he doesn't think it degrades.
3 I don't know -- I don't understand
4 what you're doing.

5 BY MS. THOMPSON:

6 Q. I'm saying if Ethicon has
7 knowledge that it degrades, is that
8 something you want to know?

9 MR. SNELL: He's already --
10 objection. Asked and answered
11 three times.

12 MS. THOMPSON: Okay. I
13 thought maybe he would change his
14 opinion on that.

15 BY MS. THOMPSON:

16 Q. Would patients want to know
17 if the material, the plastic that they're
18 putting in their bodies, degrades?

19 MR. SNELL: Objection.
20 Calls for speculation.

21 THE WITNESS: I think the
22 only thing the patients would want
23 to know is whether or not the
24 procedure worked long-term for

Marc Toggia, M.D.

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1 them.

2 BY MS. THOMPSON:

3 **Q.** Okay. So, to you, if the
4 procedure works, it doesn't really matter
5 whether that material degrades or not?

6 **A.** Absolutely.

7 **Q.** All right.

8 **A.** It does not matter to me.

9 **Q.** Thank you.

10 MS. THOMPSON: We'll take a
11 break.

12 VIDEO TECHNICIAN: We are
13 off the record. The time is 4:11
14 p.m.

15 - - -

16 (Whereupon, a brief recess
17 was taken.)

18 - - -

19 VIDEO TECHNICIAN: This
20 marks the beginning of Video
21 Number 3. We are back on the
22 record. The time is 4:38 p.m.

23 BY MS. THOMPSON:

24 **Q.** Dr. Toggia, when we went on

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1 our break, I was asking you about what
2 you tell your patients now about
3 polypropylene mesh and the TVT device.

4 Do you remember that?

5 **A.** Yes.

6 **Q.** Do you tell your patients
7 that polypropylene mesh creates a chronic
8 foreign body reaction in the body?

9 **A.** I don't tell them that,
10 because there is no evidence that it
11 causes a chronic foreign body -- counsel,
12 I'm sorry, it's staring right in front of
13 me here. I did address your question
14 about oxidation --

15 **Q.** I didn't ask you any other
16 questions, so Mr. Snell can ask you about
17 that later.

18 **A.** Okay. Thank you.

19 **Q.** So it's your opinion that
20 polypropylene mesh does not create a
21 foreign body reaction in the body?

22 **A.** My experience, in using
23 polypropylene over the last 17 years, I
24 have never seen an incidence -- an

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1 instance in which polypropylene mesh
2 caused a chronic foreign body reaction.

3 I feel that that is very
4 consistent with the long-term registries
5 trials --

6 Q. Okay.

7 A. -- that it focused on the
8 safety and looked specifically for that
9 kind of problem.

10 Q. Do you -- if Ethicon had
11 information that the mesh used in the TVT
12 creates a chronic ongoing foreign body
13 reaction, is that information that you
14 would want to know?

15 MR. SNELL: Objection.

16 Lacks foundation.

17 THE WITNESS: As a general
18 rule of thumb, I am not dependent
19 upon Ethicon to provide me with
20 any such information.

21 BY MS. THOMPSON:

22 Q. Is it information that your
23 patients would want to know?

24 A. I honestly don't believe

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1 that they would care to know.

2 Q. Do you tell your patients
3 that polypropylene mesh shrinks up to 30
4 percent?

5 A. I believe -- well, the
6 discussion is that -- and, again, within
7 the context of the TVT sling, as it was
8 used for stress incontinence, I don't
9 believe that would -- that small amount
10 of lightweight macroporous material, that
11 clinically there is a relevant amount of
12 shrinkage.

13 In the context of other
14 discussions with other base procedures,
15 there is a discussion that has to do with
16 changes in the mesh, as you stated, but
17 not for TVT sling, no.

18 Q. So the answer is, no, that
19 you don't tell your patients about
20 shrinkage of the TVT sling?

21 MR. SNELL: Objection.

22 Misstates.

23 MS. THOMPSON: Will you stop
24 the speaking objections? Just say

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1 object, and without --

2 MR. SNELL: No. No. I'm
3 allowed to state the objection to
4 form. That is a form objection.
5 Misstates.

6 MS. THOMPSON: Objection to
7 form. You can't go into all the
8 other stuff that you've been
9 doing.

10 BY MS. THOMPSON:

11 Q. Go ahead and answer the
12 question, Dr. Toglia.

13 A. It's my -- it's my expert
14 opinion that the TVT mesh does not, in
15 fact, shrink in vivo.

16 Q. Do you tell your patients
17 about the possibility of chronic pain
18 syndromes?

19 MR. SNELL: Hold on.

20 Objection. Form.

21 MS. THOMPSON: You can
22 answer, though.

23 MR. SNELL: Go ahead.

24 THE WITNESS: In the 17

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1 years that I have been implanting
2 the TVT mesh for the indication of
3 stress incontinence, in over 2,500
4 patients, let's say, I have never
5 once seen chronic pain syndrome
6 arise from the retropubic TVT
7 sling that we are discussing
8 today.

9 BY MS. THOMPSON:

10 **Q.** So you're saying you have
11 never, not one single patient, have you
12 seen a chronic pain syndrome related to
13 the retropubic TVT?

14 **A.** That's what I said.

15 **Q.** And how would you know?

16 **A.** We -- now, my practice is in
17 suburban Philadelphia, we have very high
18 rates of follow-up. Patients are seen on
19 a regular basis. They are -- they will
20 contact us with problems. We tend to see
21 the problems.

22 **Q.** When do you see your patient
23 for a postoperative checkup after a TVT?

24 **A.** Well, there are a series of

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1 evaluations that we'll see them for. The
2 first one is always within the first four
3 months or so -- excuse me, within the
4 first four weeks or so.

5 Usually, there's a second
6 follow-up within three months or so.

7 Subsequent to that, it may
8 be six or 12 months.

9 Again, you know, stress
10 incontinence, unfortunately, rarely
11 happens in isolation. These are patients
12 that have chronic pelvic floor disorders.
13 I would say, in a large number of our
14 cases, we continue to see those patients
15 annually.

16 Those patients that, at some
17 point -- or, let's say, as you said
18 earlier, were cured of their problem are
19 told that they are welcome to come back
20 with any concern that they might have.

21 Q. What is your rate of
22 follow-up with patients who receive a TVT
23 sling.

24 A. Our rate of follow-up is

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1 above the 90 percentile.

2 Q. What do you mean by "90
3 percentile"?

4 A. Excuse me, I apologize. 90
5 percent or higher.

6 Q. And how is that determined?

7 A. Because we have records and
8 we follow-up with patients after surgery
9 to make sure that they come in for their
10 scheduled visits.

11 And the ones that don't,
12 that fall through, typically are
13 contacted.

14 Q. At what point?

15 A. As I mentioned to you, I
16 think I described for you the parameters
17 for our follow-up.

18 So if somebody -- I mean,
19 obviously, there are -- you know, people
20 go on vacation, have to take care of a
21 loved one. So if they are not seen, say,
22 at that four-week mark, they're asked to
23 follow up with -- they are scheduled for
24 an appointment, say, within that

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1 three-month period of time.

2 Q. So if I requested
3 documentation of your rate of follow-up
4 on your patients who receive TVT devices,
5 could you provide that to me?

6 MR. SNELL: Objection. We
7 are not producing any of his
8 clinical records or charts, nor
9 have you produced any such thing
10 like that.

11 Your experts --

12 MS. THOMPSON: I didn't ask
13 for clinical records and charts.
14 I asked him, could he provide it.

15 And you can answer the
16 question.

17 And that's a speaking
18 objection.

19 BY MS. THOMPSON:

20 Q. Go ahead, Dr. Toggia.

21 A. I personally --

22 MR. SNELL: Actually, I'm
23 objecting and saying that will not
24 be produced. I'm putting that on

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1 the record.

2 MS. THOMPSON: I didn't ask
3 for production, did I?

4 BY MS. THOMPSON:

5 Q. Go ahead and answer, Dr.
6 Toggia.

7 Could you provide it if I
8 ask for it?

9 A. I would not provide that.

10 Q. That wasn't my question.
11 Could it be provided?

12 You've already testified that you don't
13 even know how to keep track of what
14 procedures are done --

15 A. I disagree with you,
16 counselor. I told you -- I gave you
17 specific examples --

18 Q. The record speaks for
19 itself.

20 A. -- of how --

21 MR. SNELL: Don't cut him
22 off. He's telling you -- because
23 you just -- you just threw an
24 insult at him.

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1 Go ahead and finish telling
2 her.

3 THE WITNESS: Counselor, you
4 asked --

5 MS. THOMPSON: And that's a
6 speaking objection.

7 THE WITNESS: Counselor, you
8 asked me the type of follow-up we
9 have and you specifically asked me
10 what do we do in the situation if
11 someone were to not follow up.

12 And I gave you a very
13 specific answer that the patients
14 are contacted. And, oftentimes,
15 they are contacted by myself.

16 BY MS. THOMPSON:

17 **Q.** Dr. Toggia, if you would try
18 to listen closely to my question, because
19 a lot of your answers, I'm -- I'm sorry
20 I'm losing my patience, are not the
21 answer to the question that I'm asking.
22 So if you just try to listen, we'll get
23 out a lot quicker, okay?

24 **A.** I don't always understand

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1 what it is that you're asking.

2 Q. Let's make it clear from
3 this point forward, if you don't
4 understand my question, will you ask me
5 to repeat it or rephrase, but not answer
6 a different question, okay?

7 MR. SNELL: And I'm going to
8 object to counsel's statement. I
9 think the witness has been
10 responsive. She just doesn't like
11 his answers. That's my position.

12 MS. THOMPSON: I'm loving
13 his answers. That's fine.

14 BY MS. THOMPSON:

15 Q. My question is, I asked you
16 about your rate of follow-up --

17 A. Correct.

18 Q. -- and you said it was above
19 the 90 percent mark.

20 And I'm asking you, is that
21 something that could be provided, if I
22 requested it?

23 A. It is probably something
24 that could be provided.

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1 **Q.** And what records would you
2 rely on to produce that?

3 **A.** We have medical records
4 within the practice on all of our
5 patients.

6 **Q.** So someone would have to go
7 through each record to determine when the
8 patient last saw you, when she was
9 contacted, what problems she was having,
10 correct?

11 **A.** That is correct.

12 **Q.** Okay. And are you aware of
13 literature that shows that most patients
14 with mesh complications do not return to
15 the original doctor who implanted the
16 mesh product?

17 MR. SNELL: Objection.

18 Form. Foundation.

19 THE WITNESS: I'm aware of
20 literature that would speak to the
21 opposite.

22 BY MS. THOMPSON:

23 **Q.** And what is that literature?
24 If you could tell me, please.

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1 **A.** Well, the first study, off
2 the top of my head, I believe was the
3 Abbott study, in which they commented, in
4 the conclusions, that most people did
5 return to their -- to their original
6 provider initially.

7 And I would say that,
8 regardless, that would be highly atypical
9 for my practice.

10 **Q.** How do you know that?

11 **A.** Because we have a rate of
12 follow-up that is over 90 percent.

13 **Q.** That if you went back and
14 looked at every chart of every patient
15 you've seen, you could determine whether
16 that's true or not?

17 MR. SNELL: Objection.

18 Misstates.

19 BY MS. THOMPSON:

20 **Q.** You can answer it.

21 **A.** I thought that I already
22 answered the question, I'm sorry.

23 MR. SNELL: You did.

24 BY MS. THOMPSON:

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1 Q. You can answer it again.

2 MR. SNELL: Objection.

3 Asked and answered.

4 THE WITNESS: Can I ask that
5 they simply read my answer back?

6 MR. SNELL: Yes, you may.

7 - - -

8 (Whereupon, the court
9 reporter read the following part
10 of the record:

11 "Question: And what records
12 would you rely on to produce that?

13 "Answer: We have medical
14 records within the practice on all
15 of our patients.

16 "Question: So someone would
17 have to go through each record to
18 determine when the patient last
19 saw you, when she was contacted,
20 what problems she was having,
21 correct?

22 "Answer: That is correct.")

23 - - -

24 BY MS. THOMPSON:

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1 **Q.** Do you continue to follow up
2 on patients who have left your practice,
3 one, two, three, four, five, six, seven,
4 eight, nine, ten years after the
5 procedure?

6 **A.** If they've left our
7 practice, we would have no access to
8 that.

9 But, as I've stated
10 earlier --

11 **Q.** You don't need to state
12 things that you've said earlier.

13 So if a patient has left
14 your practice because, say, they were
15 cured of their stress incontinence at
16 their follow-up visit, that's not a
17 patient that you would continue to
18 contact on a regular basis, is it?

19 MR. SNELL: Form.

20 THE WITNESS: So at the
21 point of time, let's say that a
22 patient was cured, I always offer
23 to the patient that since we've
24 done a surgical procedure that

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1 involves a permanent implant, that
2 it is my advice that they continue
3 to follow-up with us annually or
4 whether they -- any time that they
5 have a concern.

6 I also let them know that
7 I'm not going to harass them into
8 follow-up if they feel that they
9 are doing well.

10 Initially, we saw all of our
11 patients annually. And after
12 about five, six, seven years,
13 patients would literally say,
14 Doctor, can I say something to
15 you? I don't know why I have to
16 continue to come, I'm fine, it
17 costs me a co-pay to get here, I
18 have to take time off work.

19 BY MS. THOMPSON:

20 Q. So the answer to my
21 question, again --

22 A. Yes.

23 Q. -- is that you don't contact
24 patients after they've left your

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1 practice, correct?

2 MR. SNELL: Objection to
3 form. Asked and answered.

4 MS. THOMPSON: He didn't
5 answer my question, Burt.

6 MR. SNELL: You're asking
7 the same question ten times. He's
8 already told you all the different
9 things that can happen.

10 BY MS. THOMPSON:

11 Q. Do you contact your patients
12 after they've left your practice or not?

13 MR. SNELL: Same objections.

14 THE WITNESS: I'll say the
15 same thing I said previously.

16 If a patient leaves our
17 practice, and by "leaves our
18 practice," means she informs us
19 that she is no longer requiring
20 our services, it would not be
21 appropriate for us to contact that
22 patient.

23 BY MS. THOMPSON:

24 Q. All right. Could you pull

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1 the Abbott study that you referred to
2 that said strictly the opposite of what I
3 said, that most patients don't return to
4 their original implanting surgeon and
5 show me in that article what you're
6 referring to?

7 **A.** I don't think I used the
8 word "strictly."

9 MS. THOMPSON: We can go off
10 the record, please.

11 VIDEO TECHNICIAN: We are
12 off the record. The time is 4:51
13 p.m.

14 - - -

15 (Whereupon, a discussion off
16 the record occurred.)

17 - - -

18 VIDEO TECHNICIAN: We are
19 back on the video record. The
20 time is 4:54 p.m.

21 THE WITNESS: So I just want
22 to clarify if I understand you
23 correctly.

24 So what you asked me was

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1 whether or not -- you asked me
2 whether there was evidence that
3 patients that had a mesh
4 complication were unlikely to
5 return to their original provider?

6 BY MS. THOMPSON:

7 **Q.** I think what I said was the
8 majority of patients with mesh
9 complications do not return to their
10 original implanting doctor.

11 **A.** Okay. So I will correct
12 myself.

13 The Abbott study is not the
14 correct study to look at. I mis --
15 misremembered, if that's a word, that the
16 Abbott study, the majority -- or half the
17 patients have come from an outside
18 system.

19 I will -- I will now refer
20 to the registry trials, if you'll -- and
21 there are several --

22 **Q.** I'm not talking about a
23 patient that's in a trial.

24 **A.** No. Excuse me. Excuse me.

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1 I will -- when I say trial --

2 MR. SNELL: Don't interrupt
3 him when he's answering.

4 THE WITNESS: -- I mean
5 study.

6 So there are -- there are --
7 within the close -- excuse me.

8 Within closed healthcare
9 systems, an example would be
10 Kaiser, and the other would be the
11 healthcare systems of, say,
12 Finland and Austria, within those
13 closed systems, they would be able
14 to capture -- and Canada would
15 be -- would be another example,
16 they would be able to capture that
17 patient in the system no matter
18 where they ended up within the
19 system.

20 BY MS. THOMPSON:

21 Q. Are you in Kaiser?

22 A. I am not a Kaiser physician.

23 Q. Are you in Finland?

24 A. No, I'm not in Finland.

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1 Q. Are you in Austria?

2 A. No.

3 Q. Are you in Canada?

4 A. No.

5 Q. Thank you.

6 A. But that's not the question
7 that you asked me.

8 Q. You've answered my question.

9 A. I'm trying to answer the
10 question, and you're trying to prevent me
11 from answering.

12 Q. What question is on the
13 table?

14 A. You asked me whether or not
15 it is true that most patients who
16 experience a complication are not then
17 seen within the same system. And I'm
18 telling you that in those circumstances,
19 of which there is abundant data, some
20 data that goes out to ten years, that
21 that is not a correct statement. Those
22 patients are captured.

23 So, for example, if you're
24 in Finland or Austria and you had a sling

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1 complication, that -- and you sought
2 medical treatment, those are captured to
3 a high degree of specificity.

4 Q. And that's not responsive to
5 any question I asked. So we'll move on.

6 MR. SNELL: Move to strike.

7 I think it was totally responsive
8 to the question.

9 BY MS. THOMPSON:

10 Q. Do you tell your patients
11 that if they have complications that
12 require a removal of the sling, that
13 there may be multiple surgeries to
14 correct that?

15 MR. SNELL: I'm sorry, can
16 you repeat that back?

17 BY MS. THOMPSON:

18 Q. Do you tell your patients
19 that removal -- if they have
20 complications that require removal of the
21 device, it may take multiple surgeries to
22 correct it?

23 A. That is -- that is such a
24 highly -- in my practice and experience,

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1 that is such a highly unlikely
2 occurrence, that that would not -- I
3 would not speak to something that has
4 that low of an occurrence.

5 I would have difficulty
6 thinking of a patient that underwent a
7 TVT sling for the intended purpose of
8 stress incontinence that would have
9 required multiple procedures for that one
10 sole thing.

11 And in that regard, I would
12 speak to the Abbott study, in which they
13 acknowledge that for just sling-related
14 procedures, typical management of medical
15 complications were medical and not
16 surgical and that, in general, were more
17 easily -- easier resolved.

18 **Q.** Easier -- more easily
19 resolved than POP mesh?

20 **A.** Correct. But --

21 **Q.** Can you show me where in
22 Abbott it tells it -- tells you that most
23 of them are medically managed?

24 **A.** Okay. Back to the Abbott

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1 study, on Page 163, last couple column.
2 Additionally, those women with
3 complications after sling-only procedures
4 were treated more often with medical
5 management and rarely required surgical
6 re-intervention.

7 Going --

8 Q. That's comparing --

9 A. Going --

10 Q. That's comparing to the
11 prolapse mesh patients?

12 A. That was the objective of
13 the Abbott trial.

14 Second point, at the top of
15 that page. The treatment of stress
16 incontinence has a more predictable and
17 less severe course of complications
18 compared with that of synthetic mesh that
19 is used in the management of pelvic organ
20 prolapse.

21 Q. Correct, comparatively
22 speaking.

23 And the conclusion of the
24 study, just to clarify is, Most of the

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1 women who seek management of synthetic
2 mesh complication after POP or SUI
3 surgery have severe complications that
4 require surgical intervention. A
5 significant proportion require greater
6 than one surgical procedure.

7 Did I read the conclusions
8 to that study correctly?

9 A. My apologies, I wasn't
10 following you. Where -- can you tell me
11 what page you're speaking to?

12 Q. The first page, the
13 conclusions of the study. Did I read it
14 correctly? That's the only question I
15 have for you.

16 A. The comment?

17 Q. The first page of the study,
18 under conclusions, did I read that
19 correctly?

20 A. Counselor, I'm trying not to
21 be difficult, but there's not a --
22 there's not a subtitle that starts with
23 conclusions.

24 Q. In the abstract, it has,

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1 objectives, study design, results and
2 conclusion on the first page.

3 **A.** The pattern of complaints
4 differed by the index of procedure.

5 I mean, I think, you know,
6 you're taking --

7 **Q.** Most of the women --

8 **A.** You're taking it out of --

9 **Q.** Did I read it correctly?
10 Did I read the conclusions correctly?
11 That's the only question on the table.

12 **A.** The conclusions --

13 MR. SNELL: I'm going to
14 object to the form.

15 THE WITNESS: The
16 conclusions are what are listed
17 under the comment, that's the
18 conclusion.

19 BY MS. THOMPSON:

20 **Q.** I didn't ask you -- I asked
21 you, did I read --

22 **A.** You're reading the abstract.
23 You're reading an abstracted sentence.

24 **Q.** So you cannot answer the

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1 question --

2 A. I did answer the question.

3 Q. -- whether I read it

4 correctly or not?

5 A. I'm reading it under the
6 conclusion of the paper, okay? It's
7 right here. Additionally, those women
8 with complications after sling-only. We
9 are talking --

10 Q. Okay. Let's move --

11 A. -- about standalone sling
12 procedures --

13 Q. Let's move on.

14 A. -- correct?

15 Q. Let's move on.

16 Do you tell your patients
17 that the polypropylene mesh and TVT
18 device creates chronic inflammation?

19 MR. SNELL: Objection.

20 Asked and answered.

21 MS. THOMPSON: No, I asked
22 about chronic foreign body
23 reaction. Those are two different
24 things.

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1 MR. SNELL: I stand
2 corrected. I thought you said
3 that.

4 THE WITNESS: Based upon our
5 experience in the last 17 years,
6 with nearly 2,500 procedures, we
7 have not observed any chronic
8 inflammation as it relates to the
9 retropubic TVT, and, therefore, we
10 don't speak to them about
11 something that we have not seen.

12 BY MS. THOMPSON:

13 Q. If Ethicon had information
14 about chronic inflammation, is that
15 something that you, as a doctor, would
16 want to know?

17 A. As an expert in this field,
18 I would not rely upon Ethicon for that
19 information. I seek that information
20 myself, formulating that opinion from
21 high-quality studies.

22 Q. Is that information patients
23 would want to know?

24 A. I think patients would --

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1 would love to know that I spend the time
2 seeking out high-quality data and look at
3 long-term studies and rely upon those
4 type of systematic review groups when I
5 present the safety profile of that
6 procedure.

7 Q. Do any of your patients have
8 complications after a TVT procedure?

9 A. Patients can have
10 complications after any surgical
11 procedure.

12 Q. That wasn't my question.
13 Have any of your patients
14 had complications after a TVT procedure
15 that you've performed?

16 A. Yes. As I've stated in
17 my --

18 Q. Okay. That's -- that's all
19 I need.

20 And what are those
21 complications?

22 A. The most common complication
23 that we see would be injury of the
24 bladder, which, in our hands, is about 1

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1 percent.

2 Q. What else?

3 A. I believe that we did
4 discuss this earlier on, but it was
5 specific to myself.

6 There's always a risk of
7 bleeding, that is something that is
8 discussed with all patients. We tell
9 them about our experience with bleeding,
10 that we see it a little more commonly in
11 the younger patients.

12 We talk about the potential
13 risk that, maybe, the symptom improvement
14 may not be as much as they want and that
15 there are occasions where a second
16 procedure might need to be performed.

17 Conversely, we tell people
18 that there is a small risk for voiding
19 dysfunction and that, at times, that will
20 require re-intervention for that reason.

21 There is a risk for vaginal
22 perforation, urethral perforation, nerve
23 injury, bowel injury. And those are all
24 discussed with the patients.

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1 We speak about other risks
2 such as pain with sexual intercourse,
3 more specifically, relative to the other
4 procedures, and that in our experience,
5 and according to high-quality data, the
6 rate of dyspareunia is exceedingly low
7 with the retropubic TVT sling.

8 **Q.** Is it your opinion that when
9 complications occur it's because the
10 surgeon placed the device improperly?

11 **A.** I would say, in most cases,
12 it is a direct result of -- it's user
13 dependent, and I make that point in my
14 paper, in my --

15 **Q.** And that would include the
16 complications that you've had with your
17 procedures?

18 **A.** Correct.

19 **Q.** And how many TVT devices
20 have you removed or performed some kind
21 of revision surgery on?

22 **A.** I think it's best to answer
23 that sort of on an annual basis. Again,
24 understanding that I've been performing

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1 this procedure over a 17-year period of
2 time.

3 I would say, in the average
4 year, that probably ranges from zero to
5 one.

6 **Q.** So only zero to one time per
7 year are you doing any corrective surgery
8 on a TVT device?

9 MR. SNELL: Objection.

10 Misstates.

11 BY MS. THOMPSON:

12 **Q.** Zero to one per year --

13 MR. SNELL: You're changing
14 your question. You're asking
15 about TVT Retropubic and then the
16 next question is a TVT device,
17 which can be --

18 MS. THOMPSON: Sorry. I'll
19 rephrase it.

20 And, again, if you'll just
21 ask me if you don't understand a
22 question.

23 THE WITNESS: I understand.

24 MS. THOMPSON: Then you can

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1 object to form. He can ask me if
2 he doesn't understand it.

3 THE WITNESS: I'm listening
4 to what you're asking.

5 MS. THOMPSON: Because I
6 think you knew -- I think you knew
7 what I meant when I said that.

8 BY MS. THOMPSON:

9 Q. So zero to one TVT
10 Retropubic devices are how many you are
11 removing in a typical year; is that
12 correct?

13 A. Well, I don't think that
14 you're accurate, the word "removal."
15 It's removal or revision.

16 I would say that probably
17 once a year, or so, are we having to
18 surgically revise a TVT device -- excuse
19 me, a TVT procedure.

20 And I'm -- again, for the I
21 remember sake of argument, I'm speaking
22 about the retropubic TVT procedure that
23 we are doing for stress incontinence.

24 Q. In your report, you said

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1 that you are considered one of the
2 leading experts in the Greater
3 Philadelphia region on surgical revision
4 of complications related to vaginal mesh
5 procedures.

6 Is that a true -- true
7 statement?

8 **A.** That is a true statement.

9 **Q.** And why is there a need for
10 experts on surgical revision of
11 complications related to vaginal mesh
12 procedures?

13 **A.** I think there are experts
14 required for the management of any kind
15 of surgical revision of problems that can
16 occur.

17 **Q.** Now, I've never seen someone
18 say that they are an expert in the
19 surgical management of complications
20 related to a Burch or to autologous
21 fascial sling or to native tissue
22 repairs.

23 Explain to me why an expert
24 is needed for the management of vaginal

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1 mesh complications.

2 MR. SNELL: Objection.

3 Form.

4 THE WITNESS: In that
5 context, I would hold myself out
6 in those fields. The -- the need
7 to re-intervene is identical,
8 practically speaking, amongst the
9 three most common
10 anti-incontinence procedure,
11 whether that be a Burch -- I
12 probably revise more Burches,
13 fascial slings, bladder neck
14 slings than I do midurethral
15 slings.

16 BY MS. THOMPSON:

17 Q. So what you intended to say
18 is that you're one of the leading experts
19 on surgical revisions of complications
20 for any pelvic procedures, not vaginal
21 mesh procedures?

22 A. I don't -- pelvic procedures
23 is a little bit too broad.

24 With regard to prior

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1 surgical intervention for pelvic floor --
2 surgery for pelvic floor dysfunction, I
3 probably have as much experience as
4 anyone else in the area. And that is a
5 frequent source for referral.

6 Q. You, I believe, said in your
7 report that you had done 3,000 patients
8 with TVT, but that may have been all
9 urethral slings, it doesn't make too
10 much --

11 A. I think --

12 Q. -- difference for my
13 question.

14 A. Well, I think 3,000 may
15 refer to everything, including
16 sacrocolpopexy performed with mesh. I
17 think it's 3,000 mesh related procedures.
18 That would include the entire scope.

19 Q. Okay.

20 A. If you just want to accept
21 me at my word, I think that's -- I'm
22 pretty --

23 Q. We'll go ahead and find it.

24 A. That one I'm pretty sure of,

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1 because I said it.

2 Q. Well, whatever it is, it's
3 in your report. We can look it up later.

4 You said in those 3,000
5 patients --

6 MR. SNELL: Where are you
7 at, counsel? Just so --

8 MS. THOMPSON: Okay. I'll
9 have to find it. I thought I had
10 it underlined.

11 THE WITNESS: I don't think
12 I said anything beyond the fact
13 that I had experience in 3,000
14 patients. I don't think I went --
15 I did not go on.

16 BY MS. THOMPSON:

17 Q. On Page 9, the last
18 sentence. I have personally used it --
19 and I think that's referring to
20 polypropylene mesh, I guess?

21 A. That would be correct.

22 Q. -- as my primary implant
23 material in my patients for over 15 years
24 in more than 3,000 patients --

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1 **A.** That is correct.

2 **Q.** -- and have yet to observe a
3 single case -- now I want to go through
4 some of these.

5 How do you define -- define
6 "mesh rejection"?

7 **A.** Since I haven't seen a case
8 of that, a case in which there was overt
9 expulsion of the mesh, in which there was
10 complete failure of primary healing, in
11 which there was systemic response of an
12 inflammatory reaction.

13 **Q.** So your definition of
14 rejection, then, is overt expulsion and
15 not -- that would not include erosion
16 into any organ, correct?

17 **A.** My definition is just,
18 succinctly, would be evidence of overt
19 graft versus host disease.

20 **Q.** And what symptoms would the
21 patient present with --

22 **A.** Excuse me, host versus
23 graft.

24 **Q.** I knew what you meant.

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1 What symptoms would the
2 patient present with, in your opinion?

3 **A.** There could be expulsion of
4 the material, there could be complete
5 failure of primary healing, recurrent --
6 or some kind of systemic response,
7 anaphylaxis.

8 **Q.** And by "overt expulsion" you
9 are not referring to erosion into the
10 vagina, the urethra or bladder?

11 **A.** Thank you for clarifying
12 that.

13 So rejection is rejection,
14 exposure is a different phenomenon,
15 correct.

16 **Q.** And what testing did you do
17 on those 3,000 patients to determine
18 there wasn't a host versus graft
19 condition?

20 **A.** I don't think it would be
21 ethical, counselor, for me to test --
22 test -- somehow subject a test on an
23 asymptomatic patient. And I think that a
24 large body of the literature cited by

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1 your experts speak to the fact that they
2 were unable to do that kind of testing
3 because of ethical considerations.

4 Q. You would agree with me,
5 though, that rejection is an immunologic
6 response to a foreign body?

7 A. I think --

8 MR. SNELL: Objection to
9 form.

10 Go ahead.

11 THE WITNESS: I think that's
12 one -- one type of rejection might
13 be immunologic, yes.

14 BY MS. THOMPSON:

15 Q. And are you aware of
16 literature that tested, immunologically
17 and/or histologically, for a rejection
18 condition?

19 MR. SNELL: Objection to
20 form.

21 THE WITNESS: There is no
22 high-quality literature or data
23 that suggests that that phenomena
24 occurs with the TVT device when

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1 used for the indication of stress
2 incontinence.

3 The long-term registry
4 trials, which have followed out to
5 ten years, as well as the
6 additional data out to 17 years,
7 do not raise any concern,
8 clinically, that those -- that
9 that phenomena exists.

10 Now, I have reviewed the
11 information provided by your
12 experts, in which they were to
13 hypothesize that. That
14 information is Level 5 evidence.

15 Now, let me just show you
16 that.

17 BY MS. THOMPSON:

18 Q. I don't need you to show me.

19 A. No, no --

20 Q. I didn't ask --

21 A. -- I do.

22 Q. -- any question about the
23 level of evidence.

24 A. But I have to explain to

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1 you --

2 **Q.** Mr. Snell can ask you that
3 question, if you he wants to, at the end.

4 **A.** So when you have Level 1 --

5 **Q.** I have not asked you that
6 question.

7 **A.** Please allow me to finish my
8 answer, counselor.

9 When you have -- because
10 this is -- this is paramount to my
11 methodology.

12 When you have Level 1 data,
13 Level 5 data doesn't count, okay?

14 Additionally, you can never
15 derive clinical implications or draw
16 clinical conclusions from Level 5 data.
17 That is implicit in the weak design of
18 that study. Every author of those papers
19 makes that disclosure, as far as the --
20 as far as the ramifications.

21 In fact, I will point to
22 Clave, which I cited in my --

23 MS. THOMPSON: This is
24 really all nonresponsive. So

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1 if --

2 MR. SNELL: No, you asked
3 him do you know of literature.
4 And he's telling you about
5 literature.

6 THE WITNESS: Yes.

7 MR. SNELL: And he's
8 saying --

9 MS. THOMPSON: I'm asked him
10 about literature about immune
11 response to foreign body.

12 MR. SNELL: He's telling
13 you. He saw what your experts
14 have pointed to --

15 MS. COPE: Should I start
16 talking, too? You seem to speak
17 freely for him.

18 MR. SNELL: I'm not speaking
19 for him. You asked me a question,
20 Margaret, I'm going to give you an
21 answer. Don't ask me a question,
22 then.

23 MS. THOMPSON: Okay. I'm
24 going to request more time if he

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1 is going to continue to not answer
2 my question.

3 THE WITNESS: Counselor, I
4 am --

5 MS. THOMPSON: We'll go off
6 the record, and he can look up his
7 literature that he wants to talk
8 about.

9 VIDEO TECHNICIAN: We are
10 off the record. The time is 5:15
11 p.m.

12 - - -

13 (Whereupon, a discussion off
14 the record occurred.)

15 - - -

16 VIDEO TECHNICIAN: We are
17 back on the video record.

18 THE WITNESS: The literature
19 that we are discussing here is not
20 applicable to TVT, okay?

21 BY MS. THOMPSON:

22 Q. Okay. All right.

23 A. And it does not have
24 sufficient weight or evidence that you

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1 can draw those conclusions.

2 Q. Is your opinion that Level 5
3 evidence regarding safety issues is also
4 worthless?

5 MR. SNELL: Form.

6 Objection.

7 THE WITNESS: When you have
8 Level 1 evidence on safety, then
9 the Level 5 evidence is not
10 considered to be important.

11 BY MS. THOMPSON:

12 Q. Do you believe that we have
13 Level 1 evidence on the safety of the
14 TVT --

15 A. Absolutely.

16 Q. -- yes or no?

17 A. Absolutely.

18 Q. Okay. There's an article,
19 Wang, I believe it's on your reliance
20 list.

21 A. Yes.

22 Q. Do you believe that's not a
23 quality study?

24 A. That is an extremely

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1 poor-quality study.

2 Q. And is there evidence to the
3 contrary, that there is no immune --
4 significant immune response to the
5 polypropylene mesh in the TVT that you
6 are aware of?

7 A. Can I speak to --

8 MR. SNELL: Object to form.

9 THE WITNESS: Can I speak to
10 the Wang study, please?

11 BY MS. THOMPSON:

12 Q. No, I -- just answer my
13 question, please.

14 And the question is, is
15 there--

16 A. Hold on. I'm sorry, I'm
17 going to ask you to pause.

18 You did ask me about the
19 Wang study, I want to make sure --

20 Q. I asked you if you were
21 aware of it. I have not asked you any
22 questions about the Wang study, other
23 than, are you aware of it?

24 MR. SNELL: Actually, no.

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1 You --

2 THE WITNESS: You asked me
3 about the quality of the evidence.
4 I'm going to tell you the answer,
5 and I'm going to tell you what I'm
6 basing my answer on.

7 BY MS. THOMPSON:

8 **Q.** I asked you -- I'm asking
9 you about the evidence that shows that
10 there is no immune response to the
11 foreign body. That's what I would like
12 for you to answer, the question, and tell
13 me if you have evidence that there is no
14 immune response to the foreign material
15 in the TVT.

16 **A.** The long-term safety
17 studies -- excuse me. The long-term
18 Level 1 evidence studies speak to the
19 lack of a significant immune response.

20 In addition --

21 **Q.** Okay. Can you --

22 **A.** In addition --

23 MR. SNELL: Don't stop him.

24 THE WITNESS: -- the

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1 systematic reviews speak to the
2 fact, and this includes -- and
3 this is consistent with what is
4 stated by the FDA, what is stated
5 by NICE, what is stated by AUA,
6 AUGS, and SUFU, that there is --
7 that polypropylene mesh,
8 macroporous, as used with the TVT
9 device for its intended purpose,
10 is the most biomechanic --
11 biocompatible material.

12 By definition, biocompatible
13 speaks to host tolerance and the
14 lack of immunologic response.

15 BY MS. THOMPSON:

16 Q. Can you show me, in any of
17 those things that you just rattled off,
18 where it states that there is no
19 immunologic response to polypropylene
20 mesh in the TVT device?

21 MR. SNELL: Objection to
22 form.

23 BY MS. THOMPSON:

24 Q. I'm looking for immunologic

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1 response, which is what rejection or
2 graft versus -- versus host versus graft
3 response is.

4 MR. SNELL: Objection to
5 form.

6 THE WITNESS: Can we go off
7 record?

8 MS. THOMPSON: Off the
9 record, please.

10 VIDEO TECHNICIAN: We are
11 off the record. The time is 5:19
12 p.m.

13 - - -

14 (Whereupon, a discussion off
15 the record occurred.)

16 - - -

17 VIDEO TECHNICIAN: We are
18 back on the video record.

19 THE WITNESS: Yes. Again, I
20 am -- I am trying to be extremely
21 respectful of everybody's time,
22 and acknowledge that this is
23 Friday.

24 Unfortunately, the volume of

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1 material as relates to the TVT
2 device, which has been in
3 development over 20 years, is
4 broad and extensive and worldwide.
5 And, you know, unfortunately,
6 there is a lot of material.

7 And while I'm well versed in
8 it, it still takes me a while to
9 figure out exactly the location of
10 the statements that I have in
11 mind.

12 Why don't you go back off
13 the record?

14 MS. THOMPSON: I should be
15 the one who directs the
16 videographer, if you don't mind.

17 THE WITNESS: I'm sorry.
18 I'm just trying -- I'm just trying
19 to be respectful of people's time,
20 and I'm apologizing for the amount
21 of time it's taking. I'm just --
22 I want you to know I'm not doing
23 this to be obstructive.

24 BY MS. THOMPSON:

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1 **Q.** And, I mean, we can just
2 concede that you have not been able to
3 find anything on that particular issue in
4 the time allotted.

5 **A.** If I can -- if I cannot
6 produce this within the next several
7 minutes, I'm happy to move on, again, out
8 of respect for everybody's time.

9 Why don't you go ahead and
10 ask me the question, counselor?

11 **Q.** The next question?

12 **A.** No.

13 **Q.** The previous question that
14 we've been -- are we on the record?

15 MS. THOMPSON: Are we on the
16 record, Greg?

17 VIDEO TECHNICIAN: We're on
18 the record.

19 THE WITNESS: I'm sorry.

20 BY MS. THOMPSON:

21 **Q.** Are you ready to move to the
22 next question?

23 **A.** Yes.

24 **Q.** Hopefully, we won't spend as

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1 much time on the other things that you've
2 said you've not seen one single patient
3 out of your 3,000 that have had these
4 particular conditions, you said that you
5 have yet to observe a single case of
6 chronic foreign body reaction.

7 How did you determine that
8 you have not had a single patient, out of
9 3,000, that has had a chronic foreign
10 body reaction to mesh?

11 **A.** So clinical suspicions that
12 one might be experiencing a reaction that
13 would be classified as a chronic foreign
14 body reaction would be things like
15 chronic nonhealing of a wound, persistent
16 erythema, fluctuance, pain, chronic
17 drainage.

18 **Q.** But you would agree with me
19 that chronic foreign body reaction is a
20 histologic diagnosis, would you not?

21 **MR. SNELL:** Form.

22 **Objection.**

23 **THE WITNESS:** I would say
24 that it is -- it is something that

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1 always has a clinical presentation
2 and then would be confirmed on it.

3 Now, in contrast, we have
4 seen this with other implanted
5 material. So I am very familiar
6 with the presentation. In fact,
7 I've published on the
8 presentations within the pelvic
9 floor, in the vaginal space, as it
10 relates to what we referred to, at
11 the time, was chronic
12 granulomatous response to a
13 foreign body within the context of
14 reconstructive pelvic surgery.

15 BY MS. THOMPSON:

16 Q. I don't think you answered
17 my question.

18 Foreign body reaction is a
19 histologic pathologic diagnosis, correct?

20 MR. SNELL: Asked and
21 answered.

22 MS. THOMPSON: If you got
23 the answer, I sure didn't.

24 THE WITNESS: It is both.

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1 It is both.

2 MR. SNELL: Would you read

3 it --

4 THE WITNESS: It is

5 clinical --

6 MR. SNELL: Would you read

7 it back?

8 MS. THOMPSON: No.

9 MR. SNELL: Go ahead and --
10 go ahead and answer it again.

11 BY MS. THOMPSON:

12 Q. Okay. All right. So of
13 these 3,000 patients that you've never
14 seen a chronic foreign body reaction, are
15 you aware that there's literature that
16 states that 100 percent of women with
17 pelvic mesh in their bodies have a
18 chronic foreign body reaction?

19 MR. SNELL: Objection.

20 BY MS. THOMPSON:

21 Q. 100 percent?

22 Are you aware of that
23 literature?

24 MR. SNELL: Objection. Form

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1 and foundation.

2 THE WITNESS: Rephrase your
3 question, please.

4 BY MS. THOMPSON:

5 Q. Are you aware -- are you
6 aware of literature that states that 100
7 percent of women with pelvic mesh have a
8 chronic foreign body reaction to the
9 mesh?

10 MR. SNELL: Same objection
11 to form and foundation.

12 THE WITNESS: If you have a
13 foreign body implanted in your
14 body, chronically, there will
15 always be histologic evidence of
16 the body's reaction surrounding
17 the mesh or the material.

18 BY MS. THOMPSON:

19 Q. So that's really --

20 A. That -- that is not germane
21 or related clinically, nor can you take
22 inflammation that just randomly produces
23 that kind of in vitro, again, Level 5
24 evidence, you cannot make clinical

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1 inference. There's not enough power to
2 that study.

3 The only way that you could
4 make that is by examining Level 1
5 evidence and deriving that.

6 Q. Is there Level 1 evidence
7 that states that there is not a chronic
8 foreign body reaction to mesh; yes or no?

9 A. There is -- there is a
10 chronic -- excuse me.

11 There is -- the body does
12 respond, in 100 percent of patients, but
13 there's no negative clinical sequelae.

14 Q. So your statement that you
15 have not had a single case of chronic
16 foreign body reaction, that's not really
17 what you mean, right?

18 A. No, clinically based. I'm
19 speaking to clinical medicine, clinical
20 problems.

21 Q. And you know that for a
22 fact, out of your 3,000 patients?

23 A. To the best of my knowledge,
24 a patient has never presented to me with

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1 a chronic or acute medical syndrome in
2 which we could identify, as the source, a
3 chronic inflammatory reaction.

4 Q. And I think that's a little
5 different from what you stated here --

6 A. No, counselor.

7 Q. -- so I appreciate that.

8 A. No. My -- my -- if I speak
9 to my clinical experience, it's clinical.
10 It's not stuff that I'm doing in a lab.
11 I think that's quite clear.

12 Q. Is less than Level 1
13 evidence important if you're reporting a
14 death from a minor procedure like the
15 TVT?

16 MR. SNELL: Objection to
17 form.

18 THE WITNESS: Well, I
19 think -- I think you're using -- I
20 think you're using the -- I think
21 that you're using the clinical --
22 clinical evidence pyramid out of
23 context here.

24 All deaths are important.

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1 There is no non-important death.

2 You don't -- you don't need Level

3 1 evidence to tell you that a

4 death has occurred.

5 BY MS. THOMPSON:

6 Q. And that's something that

7 you would want to know, correct?

8 MR. SNELL: Objection.

9 BY MS. THOMPSON:

10 Q. As a doctor and a patient?

11 MR. SNELL: Objection.

12 Form.

13 THE WITNESS: If a patient
14 of mine were to die as a result of
15 one of my procedures, I would
16 absolutely want to know about the
17 occurrence of the death and the
18 cause of death.

19 BY MS. THOMPSON:

20 Q. I'm talking about published
21 in the literature.

22 Would you want to know other
23 doctors' patients who have died as a
24 result of a TVT or another mesh

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1 procedure?

2 MR. SNELL: Object to form.

3 THE WITNESS: You know, I

4 think that I would be aware of

5 that, yes.

6 BY MS. THOMPSON:

7 Q. That wasn't my question,

8 would you be aware of it.

9 Is it something that you

10 would want to know and see published?

11 MR. SNELL: Same objection.

12 THE WITNESS: I don't

13 necessarily think it needs to be

14 published. If someone dies at the

15 hospital next to me, I'm not going

16 to wait until it's published

17 before I think about what had

18 occurred.

19 BY MS. THOMPSON:

20 Q. Well, what if a patient dies

21 in Atlanta, Georgia, which happened a

22 little while ago, is that something that

23 you would want to know about?

24 MR. SNELL: Objection.

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1 Form. Vague. Lacks foundation.

2 THE WITNESS: I don't --

3 BY MS. THOMPSON:

4 Q. From a TVT.

5 A. I don't know -- I mean, that
6 an isolated case that happened
7 elsewhere -- I mean, would I want to
8 know? I mean, I wouldn't close my ears
9 if someone told me about the problem.

10 But had I not heard about
11 it, I wouldn't say that a foul was
12 committed.

13 Q. Do you routinely send the
14 specimens that you remove when you -- of
15 mesh for histologic exam?

16 A. We do routinely send -- send
17 specimens to the lab for identification.

18 Q. Have you ever looked at the
19 slides?

20 A. I have not looked at the
21 slides.

22 Q. You've never looked at an
23 explanted mesh under the microscope?

24 A. I have never looked at an

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1 explanted mesh under the microscope.

2 Q. So you really don't know
3 what they look like, do you, under the
4 microscope?

5 A. Yes, I do. They are in all
6 these articles. There are clear
7 photomicrographs on there with accurate
8 pathologic descriptions. That's not what
9 you asked me.

10 Q. But you disagree with the
11 pathological descriptions in the
12 literature?

13 A. You and I are talking about
14 different things.

15 I have already told you that
16 a foreign material in the body, you will
17 see evidence of that response. You have
18 to see evidence. There -- it's a foreign
19 body and there is -- and there is a
20 thing.

21 But it's not a clinically
22 significant observation.

23 Q. All right. You agree with
24 me that there are alternatives to

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1 midurethral slings?

2 MR. SNELL: Form.

3 THE WITNESS: In what

4 context? In the treatment of

5 stress urinary incontinence in

6 women?

7 BY MS. THOMPSON:

8 Q. In the treatment of stress
9 urinary incontinence?

10 A. TVT is only one of several
11 procedures that is effective for the
12 treatment of female stress incontinence.

13 Q. Okay. The Burch procedure
14 would be one of those, correct?

15 A. That is correct.

16 Q. And an autologous sling
17 would be one of those, correct?

18 A. That is correct.

19 Q. And there are actually
20 nonsurgical treatments for stress urinary
21 incontinence as well, correct?

22 A. That's correct.

23 Q. And can we agree that they
24 have equivalent efficacy?

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1 **A.** Across the board, efficacy
2 is similar. Again, you do a
3 meta-analysis, you overweight
4 higher-quality data, you'll get -- you'll
5 get recommendations that say, I favor one
6 or the other.

7 But I think it's a
8 reasonable statement, as presented in the
9 short-term, that the effectiveness, in
10 the short-term across the procedures
11 are -- demonstrate similar efficacy.

12 **Q.** Do you know Mickey Curran?

13 **A.** Yes.

14 **Q.** I believe you've published
15 with him on one of your papers; is that
16 correct?

17 **A.** I've published with Mickey
18 on several papers, correct.

19 **Q.** I want to read you and
20 statement and I want you to tell me
21 whether you agree with it or not, okay?

22 **A.** May I ask who is making the
23 statement?

24 **Q.** Well, Dr. Curran is making

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1 the statement.

2 **A.** Thank you. I just want to
3 make sure it wasn't me making the
4 statement.

5 **Q.** But it wouldn't matter, I
6 guess, for the purpose of whether you
7 agree with it or not.

8 In our opinion, the
9 autologous pubovaginal sling is
10 appropriate for patients with stress
11 urinary incontinence who declined to have
12 synthetic material implanted because of
13 concerns related to long-term placement
14 of synthetic mesh.

15 Would you agree with that
16 statement?

17 MR. SNELL: Objection to the
18 form.

19 Go ahead.

20 THE WITNESS: Can you tell
21 me the year that that was
22 published?

23 MS. THOMPSON: 2012, I
24 believe.

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1 THE WITNESS: I think that's
2 a relatively reasonable statement.

3 BY MS. THOMPSON:

4 Q. Reasonable?

5 A. Yes.

6 Q. Okay. Thank you. I'll just
7 check on that date for you real quick.
8 2012.

9 A. Okay. Thank you.

10 Q. How much are you paid for
11 placing a TVT on average?

12 A. The reimbursement for the
13 TVT -- there is no -- there is no
14 specific procedure of TVT. So it's a
15 pubovaginal sling procedure.

16 So if I place an autologous
17 fascial sling or if I do a synthetic
18 midurethral sling, the reimbursement is
19 about the same. You know, Medicare data,
20 with geographic area factors factored in,
21 in this region, I would say probably the
22 range is \$800 to, maybe, \$1,200 a
23 procedure.

24 Q. And how much would you be

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1 paid for a Burch?

2 **A.** I would suspect that the
3 reimbursement for the Burch is likely to
4 be a little bit higher.

5 But I do want to -- I do
6 want to clarify something. And I suspect
7 that with your background, you would
8 understand what I'm about to say.

9 We're not paid for the
10 procedure. The reimbursement for, say,
11 the surgery encompasses all services that
12 we provide, 24 hours prior to the
13 procedure for the actual procedure,
14 whatever amount of postoperative care is
15 deemed necessary and pretty much all care
16 out to about 90 days.

17 So the percentage of what I
18 just mentioned that's specific for
19 placing the procedure, it's probably half
20 that, if you're looking for that specific
21 of information.

22 **Q.** And how long did it take you
23 to place a TVT?

24 **A.** In my hands, a TVT can be

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1 placed in about 20 minutes.

2 Q. And how about an autologous
3 sling -- well, let me ask you this first:
4 Are you performing any autologous sling
5 procedures?

6 A. In our practice, we don't
7 currently perform autologous fascial
8 slings in the last several years, because
9 we reserve those for a certain subset of
10 patients. And, fortunately, we've not
11 had to go that far down the algorithm.

12 Q. So it's been several years
13 since you've placed an autologous -- or
14 since you've performed an autologous --

15 A. That's correct.

16 Q. -- sling procedure?
17 How about the last time you
18 were -- performed a Burch procedure.

19 A. The last time I performed a
20 Burch procedure might be 2002.

21 Q. But you were trained on both
22 of those procedures, correct?

23 A. Of course.

24 Q. Do you teach residents and

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1 fellows?

2 **A.** I do. I don't teach
3 fellows, excuse me.

4 **Q.** You teach residents?

5 **A.** Correct.

6 **Q.** At Thomas Jefferson?

7 **A.** No. Lankenau Medical Center
8 has an independent residency.

9 **Q.** And I presume, since you're
10 not performing a Burch or autologous
11 sling, you're probably not teaching those
12 to the residents currently?

13 **A.** To be honest with you,
14 excuse me, I'm sorry. I may have
15 misspoke, as far as the last time I
16 performed a Burch.

17 When we're having this
18 conversation, I'm thinking of standalone
19 procedures. There may be combination
20 procedures that we're doing it.

21 I'll be very honest with
22 you, I don't train -- the residents come
23 to me for, really, basic training. We
24 don't really train them to go on and

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1 independently perform a procedure like an
2 autologous fascial sling or a Burch.
3 They -- their role, in that kind of a
4 setting, would be more observation or
5 assistance.

6 Q. Thanks. I know we talked a
7 lot about studies, and I have a few
8 questions that I want to ask you that I
9 think will be relatively simple.

10 And I know, from talking
11 with you today, that you feel like
12 clinical studies are important, correct?

13 A. I think that levels of
14 evidence are important.

15 Q. And you've actually
16 performed and published, including some
17 randomized control trials, correct?

18 A. That's correct.

19 Q. And they're -- you would
20 agree with me that they are important so
21 that doctors can make responsible
22 treatment decisions, right?

23 A. I think that, again, the
24 levels of evidence provided by clinical

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1 studies are important, yes, in how we
2 practice medicine and how we -- how we
3 make clinical decisions.

4 Q. And it's important for
5 patients so that they can give informed
6 consent, correct?

7 A. Yes.

8 Q. Some noncontroversial
9 questions.

10 And when you're looking at
11 clinical studies, you want to see safety,
12 correct?

13 A. It depends upon the context
14 of the study.

15 Q. But in general, as a -- you
16 know, broadly speaking you want to know
17 the product is effective, correct?

18 A. You know, again, within the
19 context of that part of medicine that I
20 practice as it pertains to surgery, we
21 would phrase it, it's the balance between
22 risk and benefit.

23 Q. Okay. So you want
24 studies --

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1 **A.** Surgery -- and safety, of
2 course, would straddle risk and benefit.

3 **Q.** I agree. And that's fine.

4 **A.** And it's relative.

5 **Q.** And I'm -- I'm happy to talk
6 about to it -- talk it in terms of risk
7 or complications and benefit or --

8 **A.** Yes.

9 **Q.** -- treatment success.

10 And when you're looking at a
11 study, regardless of the level, you want
12 it to provide accurate information,
13 correct?

14 **A.** I'm not sure I understand
15 what you're implying by the term
16 "accurate."

17 **Q.** You want the data that's
18 presented to be correct? You want it to
19 be -- what the study actually found is
20 what you want to read when you're reading
21 the publication, correct?

22 MR. SNELL: Form.

23 THE WITNESS: And I

24 apologize, you know, I am an

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1 editor within this sphere, so --

2 BY MS. THOMPSON:

3 Q. So you're an editor of IUJ?

4 A. Correct.

5 Q. And also Female Pelvic

6 Medicine; is that correct?

7 A. And Reconstructive Surgery,
8 it's one journal.

9 Q. I just didn't want to say
10 the whole thing, I'm getting tired.

11 A. It took several decades to
12 come up with that, so I do appreciate if
13 you do say it.

14 Q. Okay, I will --

15 A. You can say FMPRS.

16 Q. I will from now on.

17 A. Thank you. I worked very
18 hard for that, as you can imagine.

19 Q. When did you last review an
20 article or IUJ?

21 A. It's within the last few
22 weeks.

23 Q. Was that a mesh article?

24 A. The one in the last couple

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1 of weeks, I do not -- I know I've
2 reviewed some mesh related articles
3 within the past month, but the one in the
4 last couple of weeks -- sometimes there's
5 mesh involved, but that's not the primary
6 objection, so --

7 Q. Well, you would agree with
8 me, as an editor --

9 A. Excuse me. I'm sorry. I
10 would say within the last three weeks,
11 yes, I have reviewed an article primarily
12 on mesh related procedures in this
13 sphere.

14 Q. And what was -- what was the
15 gist of that article, if you can divulge
16 it?

17 A. So as you're well aware, the
18 International Journal is an international
19 journal, and so many of the submissions
20 come from other countries. Many of the
21 ones that I look at come either from the
22 Middle East or China or one of the
23 southeast, you know, Asian companies.

24 Oftentimes we get

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1 manuscripts that relate to a particular
2 center or individual's experience with a
3 procedure. Oftentimes it's some variant
4 of a procedure. And so, typically, it's
5 looking at -- it's looking at that.

6 Q. And you can't give -- be any
7 more --

8 A. Anti-incontinence procedure
9 that involved some kind of mesh related
10 material.

11 And, again, I'm not giving
12 you the name because it doesn't really
13 have a name, it's something that they
14 came up with themselves as an
15 alternative.

16 Q. Okay. And you want the
17 studies that you look at to be objective,
18 right?

19 A. You and I can spend hours
20 talking about whether anything is ever
21 objective in this sphere. What we hope
22 is that the studies are well defined,
23 such that biases are apparent and that
24 you minimize the unrecognized biases.

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1 So, yes, we look at that.

2 Q. So as objective as it can be
3 under the constraints that it might have?

4 A. And what goes along with
5 that is that the -- that the endpoints,
6 for example, are objective. You know,
7 that these are not studies, say, for
8 example, somebody picked up a telephone
9 four years or five years later, called up
10 patients and asked them a series of
11 simple questions and then determined
12 that -- determined the rate of success or
13 not success based on that.

14 You would prefer to have
15 objective data.

16 Q. Okay. So objective data, to
17 the extent possible, you want to minimize
18 bias or disclose bias, if it exists,
19 correct?

20 A. Correct.

21 Q. And you shouldn't decide
22 what the results are going to be before
23 you get the results, correct?

24 A. You shouldn't, but that's

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1 often the case.

2 Q. Would that cause you some
3 concern if you reviewed a study, as an
4 editor of one of those journals, that the
5 results were predetermined?

6 A. I think that's a
7 different --

8 MR. SNELL: Form.

9 THE WITNESS: I'm sorry.

10 I think that's different
11 than what I just interpreted.

12 I don't think -- no, I don't
13 agree -- I don't agree that
14 results are predetermined in the
15 stuff that we look at. I think
16 that there's always, you know --
17 there's always a bias of what the
18 results mean or what -- you know,
19 what the results mean.

20 So, yes, I mean, my -- my
21 job, as an editor, is to read a
22 study and to determine, did the
23 study have a primary objective,
24 did -- was the design sufficient

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1 that they could comment on that
2 objective; and, more importantly,
3 when looking at the results, do
4 they accurately interpret the
5 significance of those results.

6 BY MS. THOMPSON:

7 Q. What would you do if you
8 were an editor and received a paper where
9 the results were predetermined?

10 MR. SNELL: Form.

11 Incomplete --

12 THE WITNESS: I don't
13 know -- I don't understand --

14 MR. SNELL: -- hypothetical.

15 MS. THOMPSON: Sorry?

16 THE WITNESS: -- how I would
17 know they were predetermined.

18 MR. SNELL: Incomplete
19 hypothetical.

20 MS. THOMPSON: I'm going to
21 give you -- --

22 THE WITNESS: If the results
23 are predetermined, you wouldn't
24 need a study.

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1 - - -

2 (Whereupon, Exhibit
3 Toglia-7, Bates ETH.MESH 05225354,
4 05225380-384; TVT Instructions for
5 Use, was marked for
6 identification.)

7 - - -

8 BY MS. THOMPSON:

9 Q. Dr. Toglia, have you seen
10 this document from Ethicon before?

11 MR. SNELL: I'm going to
12 object. This is part of a larger
13 document that has been provided.
14 You're just cutting two pages.

15 MS. THOMPSON: And we can
16 get the larger document, if you
17 want him to have it for this
18 purpose.

19 MR. SNELL: I'm sure it's
20 here somewhere in the files.

21 MS. THOMPSON: Okay. If you
22 want him to see it, you're welcome
23 to pull it out.

24 THE WITNESS: Again, I mean,

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1 I'm not -- I don't know --
2 understand the context of what
3 this is describing. I'm familiar
4 with the --

5 BY MS. THOMPSON:

6 Q. Well, let me ask you this:
7 Dr. Toglia --

8 A. Yes.

9 Q. -- did you see the contract
10 with -- between Ethicon and Drs. Olmstead
11 and Nielsen?

12 MR. SNELL: Hold on.

13 Objection. Foundation and form.
14 And that actually misstates the
15 evidence.

16 Go ahead.

17 THE WITNESS: I believe that
18 that's outside the sphere of the
19 task that I was given to look at
20 the design and the safety of the
21 TVT device.

22 BY MS. THOMPSON:

23 Q. I believe Dr. -- Mr. Snell
24 said that you had this -- the contract

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1 that this is the attachment to.

2 **A.** I'm not -- I'm not telling
3 you that I'm not familiar with this
4 document or that I may not have perused
5 this document.

6 However, I may not have -- I
7 may not have committed to memory, you
8 know, the details of these things.

9 I mean, I've looked at
10 thousands of things.

11 **Q.** Let's read through it.

12 **A.** But for intents and
13 purposes, you know, I would not say that
14 I could speak to the details of what you
15 presented to me.

16 **Q.** So you're not giving
17 opinions as to the Olmstead studies
18 regarding TVT?

19 MR. SNELL: Actually,
20 objection.

21 THE WITNESS: I think I've
22 given opinions within my expert
23 reports. I'd be happy to pause
24 and point them out to you, if

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1 you'd like, counselor.

2 BY MS. THOMPSON:

3 **Q.** I guess I just misunderstood
4 your answer.

5 **A.** Yes.

6 **Q.** Let me -- let me just -- so
7 this exhibit states, The results of the
8 clinical trials will be considered
9 acceptable if, first, they do not differ
10 significantly from the results published
11 in the original article.

12 To you, is that an
13 appropriate study design?

14 MR. SNELL: Objection.

15 Misstates. Form.

16 THE WITNESS: This doesn't
17 refer to that, counselor. This is
18 not -- I mean, this is not saying
19 that it's acceptable to -- for
20 publication, that -- this
21 doesn't -- I mean, the fact that
22 it speaks to the results has
23 nothing to do with the design.

24 I -- may I give you my

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1 interpretation of what we're
2 looking at here?

3 BY MS. THOMPSON:

4 **Q.** No, you don't need to give
5 me your interpretation. I'll ask you --

6 **A.** You've asked me about this
7 document.

8 **Q.** -- you a question and you
9 can answer it.

10 So if the investigators were
11 only paid if these objectives were met,
12 would that be an appropriate design for a
13 clinical study?

14 MR. SNELL: Objection to
15 form.

16 MS. THOMPSON: That's a
17 hypothetical.

18 THE WITNESS: Yes, I
19 understand. My -- let's make sure
20 we're talking about the same
21 studies.

22 My understanding is that
23 this is referring to the
24 multicenter studies on the TVT

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1 device and that Olmstead did
2 not -- was not a participating
3 site in the multicenter study.
4 But Olmstead was the individual
5 becoming -- who was being paid.

6 Am I correct?

7 BY MS. THOMPSON:

8 Q. Who told you that? Or where
9 did you come up with that?

10 A. Nobody told me that. That
11 was just -- I'm just asking you, that was
12 kind of my -- that's kind of where I'm
13 coming from.

14 Can you show me the specific
15 study that we're referring to here?

16 Q. Mr. Snell -- I'm just asking
17 you about this contract.

18 A. I'm asking you whether you
19 can show me -- I don't know what this is
20 connected to, what study this is
21 connected to.

22 Q. There have been multiple
23 studies that have been published --

24 A. Right.

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1 **Q.** -- from the original
2 cohort --

3 **A.** Right.

4 **Q.** -- correct?

5 MR. SNELL: Objection.

6 Form. Vague.

7 THE WITNESS: I will answer
8 that question.

9 The original -- I don't
10 know -- the original Olmstead
11 study involved, I think, roughly
12 about 50 patients. I don't -- I'm
13 aware of the longitudinal studies
14 where Nielsen published on the
15 same cohort of patients at a year,
16 two years, five years, seven
17 years, you know, ten years, et
18 cetera, twelve years, et cetera,
19 et cetera, so on, 11.5 years, 17
20 years.

21 That's not -- I'm just
22 clarifying. That's not the same
23 as Olmstead. Olmstead's original
24 report was a series of, I think,

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1 roughly 50 patients that he
2 himself operated on.

3 And I don't believe that
4 this document refers back to that
5 original study.

6 BY MS. THOMPSON:

7 Q. Is this -- is it an
8 appropriate study design where the
9 investigator is paid if certain criteria
10 are met when the results are published?

11 MR. SNELL: Objection to
12 form. Misstates the evidence.

13 THE WITNESS: I don't --

14 MR. SNELL: Asked and
15 answered.

16 THE WITNESS: I don't know
17 how to answer that. I'm sorry.

18 BY MS. THOMPSON:

19 Q. So you don't know how to
20 answer a question about you're only going
21 to get paid if you get these results?

22 MR. SNELL: Hold on.

23 Objection. Argumentative.

24 MS. THOMPSON: I'm just

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1 trying to understand his answer.

2 THE WITNESS: No, no, I
3 understand.

4 And, counselor, I understand
5 that you are -- here is my problem
6 and my confusion, okay? You are,
7 at the same time, asking me a very
8 general question about things I do
9 as an editor in science in
10 general.

11 At the same time, you're
12 putting a very specific document,
13 in isolation, and not providing me
14 with the reference study and
15 you're asking me to make a comment
16 in the middle that seems to link
17 one with the other.

18 And I'm telling you, I'm not
19 able to -- I don't know how -- not
20 that I'm -- not that I'm will --
21 I'm not willing to, I don't know
22 how to make an answer about a
23 study that I don't know -- don't
24 know anything about.

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1 BY MS. THOMPSON:

2 Q. I'm only talking about the
3 design of a study.

4 Is this an appropriate
5 design of a study?

6 MR. SNELL: Objection to
7 form.

8 THE WITNESS: This paper
9 does not address a design of the
10 study. This paper does not
11 stipulate if the study is not
12 designed to our satisfaction,
13 they'll be no reimbursement. This
14 study speaks to results.

15 BY MS. THOMPSON:

16 Q. Okay. We'll move on.

17 A. And the results have nothing
18 to do with the design. Nor do I see a
19 phrase that says, the study has to be
20 designed such that these results must
21 be --

22 Q. No. It's just the
23 investigator wasn't paid if the results
24 weren't -- weren't met.

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1 MR. SNELL: Objection. Move
2 to strike.

3 BY MS. THOMPSON:

4 Q. Were you shown -- prior to
5 working in this lawsuit, were you shown
6 the material safety data sheet related to
7 the polypropylene used in Ethicon mesh
8 devices? And you're a chemist, you know
9 what a material safety data sheet is --

10 A. I do.

11 Q. -- correct?

12 A. I do.

13 No. I did not -- I did not
14 previously look at that material.

15 - - -

16 (Whereupon, Exhibit
17 Toggia-8, ETH.MESH 08696131-132,
18 Exhibit C - Clinical Trials, was
19 marked for identification.)

20 - - -

21 THE WITNESS: We're talking
22 specifically about regulatory
23 paperwork. This is non-clinical
24 regulatory type stuff.

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1 MS. THOMPSON: I don't think
2 there was a question pending, but
3 I don't think -- sorry. I don't
4 think the material safety data
5 sheet is a regulatory document.

6 BY MS. THOMPSON:

7 Q. Okay. Have you seen the
8 material safety data sheet now, since
9 you've been working on this lawsuit?

10 A. Yes. This was part of
11 the -- this was part of the materials
12 provided to me.

13 Q. And I'll direct your
14 attention to Number 10 in the material
15 safety data sheet regarding stability and
16 reactivity.

17 A. Yes.

18 Q. Could you read the sentences
19 under incompatibility?

20 A. The following materials are
21 incompatible with this product. Strong
22 oxidizers, such as chlorine, peroxides,
23 chromates, nitric acid, perchlorates,
24 concentrated oxygen, sodium hypochlorite,

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1 calcium hypochlorite, permanganates,
2 chlorine and nitric acid.

3 Q. And are those compounds
4 found in the human body?

5 A. Within the context of this
6 type of testing, I would say they are
7 probably not. And I don't see -- I don't
8 see anything that says that -- that
9 references in concentrations normally
10 found within human tissue.

11 Q. And under Number 15, other
12 information --

13 A. Yes.

14 Q. -- component toxicity, could
15 you read the sentences after that?

16 A. Sure. Polypropylene has
17 been tested in laboratory rats by
18 subcutaneous implants of disc or powder.
19 Local sarcomas were induced at the site
20 of implantation. No epidemiologic
21 studies or case reports suggest any
22 serious chronic health hazards from
23 long-term exposure to polypropylene
24 decomposition products below the

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1 irritation level.

2 Q. Did Ethicon perform any
3 studies to determine whether or not the
4 polypropylene used in their mesh devices
5 causes sarcoma in humans?

6 A. I don't see that -- that
7 discs of polypropylene or powders of
8 polypropylene have anything to do with
9 the TVT device when used for its proper
10 indication of stress incontinence in
11 women.

12 I think that the science in
13 this area, it is well known that the
14 formation of sarcoma is related to form,
15 form material, and that you can't
16 extrapolate from laboratory rats to
17 humans.

18 Q. So the answer is you're not
19 aware of any studies that Ethicon did to
20 determine whether a TVT mesh could lead
21 to sarcoma?

22 A. Let me just refer to my
23 report for a second.

24 I think it's fair to say

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1 that they did not, but I don't see -- I
2 wouldn't understand why that would be --
3 why that would be relevant.

4 **Q.** Is this information
5 something you would want to know, as a
6 physician?

7 MR. SNELL: Objection to
8 form.

9 THE WITNESS: Maybe if I was
10 a veterinarian caring for rats and
11 I was implanting discs or powders.

12 But this information is not
13 pertinent or clinically relevant.

14 BY MS. THOMPSON:

15 **Q.** Is this information about
16 the polypropylene used in the Ethicon
17 pelvic mesh products something that
18 patients should be informed of?

19 MR. SNELL: Same objection.

20 THE WITNESS: To the best of
21 my knowledge, polypropylene discs
22 or powders are not used in the TVT
23 product. And at the same time,
24 the TVT product is not used in

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1 rats.

2 BY MS. THOMPSON:

3 Q. But the fact that the disc
4 and powder in rats may cause cancer is
5 irrelevant, in your opinion?

6 A. I think animal studies have
7 established that -- that it's related to
8 both the -- the animal and the form and
9 that it is not transferable to humans.

10 Q. Are you familiar with the
11 term "latency period"?

12 A. Yes.

13 Q. Do you know what the latency
14 period for exposure and development of
15 sarcoma is thought to be in humans?

16 A. No, I'm not.

17 Q. Would it surprise you if
18 it's 30 years?

19 MR. SNELL: Form. Vague.
20 Lacks foundation.

21 THE WITNESS: It probably
22 would surprise me, yes.

23 BY MS. THOMPSON:

24 Q. Has a TVT been implanted in

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1 a human for 30 years?

2 **A.** If the first clinical trials
3 of a TVT were published somewhere around
4 '96, we would be 20 years. Did I do that
5 wrong? I was thinking '86.

6 We are probably a few --
7 we're probably a few years shy of that.

8 **Q.** All right. I'm going to ask
9 you about whether or not you had seen any
10 documents or whether Ethicon had told you
11 about certain things prior to your
12 involvement in this lawsuit, okay?

13 **A.** Okay.

14 **Q.** Is that -- do you
15 understand?

16 MR. SNELL: Can I say one
17 thing? Off the record.

18 VIDEO TECHNICIAN: We are
19 off the record. The time is 6:04
20 p.m.

21 - - -

22 (Whereupon, a brief recess
23 was taken.)

24 - - -

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1 VIDEO TECHNICIAN: This
2 marks the beginning of Video
3 Number 4. We are back on the
4 record. The time is 6:06 p.m.

5 BY MS. THOMPSON:

6 Q. So, Dr. Toggia, I'm going to
7 ask you some questions about whether you
8 either saw documents or Ethicon told you
9 about certain things. And this would all
10 be prior to your involvement in this
11 lawsuit.

12 A. Yes.

13 Q. Did Ethicon tell you that
14 mechanically cut mesh thins or stretches
15 when it's placed under tension?

16 MR. SNELL: Form.

17 THE WITNESS: I don't need
18 Ethicon to tell me about the
19 properties of the material, given
20 that I handle it on a frequent
21 basis.

22 BY MS. THOMPSON:

23 Q. And other doctors don't need
24 that information either?

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1 **A.** I'm sorry, I don't see the
2 relationship to that -- the question.

3 **Q.** Is it your opinion that
4 doctors generally don't need the
5 information that Ethicon has about the
6 mechanically cut mesh thinning --

7 **A.** All right.

8 **Q.** -- and stretching on
9 tension?

10 **A.** So we're no longer talking
11 about what you said that we're going to
12 talk about, which was Ethicon's
13 communication with me on this material?
14 Are we done with that?

15 **Q.** Well, on this particular
16 item, I want to know whether you think --
17 you said it's not -- you don't need to
18 hear it from Ethicon.

19 **A.** Correct.

20 **Q.** I'm asking you, do other
21 doctors need to hear it or would want to
22 hear it from Ethicon?

23 MR. SNELL: Form.

24 THE WITNESS: I don't

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1 know -- I don't know what other
2 doctors would need or want to
3 hear. I think that, you know, in
4 the -- prior to my involvement in
5 this matter, there were
6 discussions amongst physicians and
7 Ethicon engineers, and other
8 people, where we discussed the
9 properties of mechanically cut
10 mesh and how it behaves under both
11 physiologic and nonphysiologic,
12 you know, circumstances.

13 I would say, again, as a
14 surgeon, the nonphysiologic stuff
15 really is of no clinical meaning,
16 nor do I think that you can infer
17 any kind of clinical importance to
18 that information.

19 BY MS. THOMPSON:

20 Q. Okay. And even if Ethicon
21 thought it was clinically important, you
22 didn't feel like you needed to have that
23 information?

24 MR. SNELL: Form.

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1 THE WITNESS: Again, I don't
2 rely upon Ethicon to tell -- to
3 provide me with information as it
4 relates to how I manage patients
5 or the materials that I use.

6 BY MS. THOMPSON:

7 Q. And you're not -- you do not
8 feel like you can give an opinion as to
9 whether other doctors would want to or
10 need that information?

11 A. I think that's beyond the
12 scope of what I've prepared, yes.

13 Q. Okay. Did Ethicon, and
14 there are going to be a whole bunch of
15 these, so if your answer is the same we
16 can kind of go with that.

17 A. I don't know what you're
18 going to ask me.

19 Q. Did Ethicon tell you or show
20 you documents showing fraying of
21 mechanically cut mesh?

22 MR. SNELL: Form.

23 Go ahead.

24 THE WITNESS: I've seen

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1 documents that -- I don't know
2 that I would use the word
3 "fraying," per se. I think you're
4 implying, you know -- or labeling,
5 per se.

6 BY MS. THOMPSON:

7 Q. You've never seen documents
8 that use the word "fraying"?

9 A. No, there are documents that
10 use the word "fraying."

11 Q. Ethicon documents?

12 A. There are Ethicon documents
13 that use the word "fraying." I have seen
14 those documents.

15 Q. So, at least, people at
16 Ethicon called it fraying?

17 A. Yeah. I just -- I just --
18 what's the working definition of fraying?
19 Is your definition of fraying the same as
20 mine? The same as theirs?

21 Q. But is that the same, in
22 your opinion, that that -- that
23 information is irrelevant to you in your
24 practice?

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1 **A.** No. I don't think that's
2 what I'm speaking to. Information is
3 relevant. Whether it's relevant that
4 Ethicon absolutely had to communicate
5 one-on-one with me on that particular
6 issue is what I'm speaking about.

7 **Q.** I don't -- I don't think I
8 asked about one-on-one.

9 I'm just asking you, is that
10 information that you would have liked to
11 have known, if Ethicon had that
12 information?

13 **A.** I did know about that
14 information, and I did receive that
15 information from Ethicon.

16 **Q.** Okay. And did other doctors
17 receive that information --

18 **A.** Yes.

19 **Q.** -- that mechanically cut
20 mesh frayed?

21 **A.** Yes.

22 **Q.** Did you teach about that
23 when you were doing your courses or doing
24 your preceptor training?

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1 **A.** Well, again, the fraying
2 occurred at nonphysiologic, you know,
3 forces. And so, yes, I think that we did
4 talk about mesh, its properties, its
5 behavior, how the -- how -- why it was
6 important to adhere to the well-described
7 steps of the procedure in order for the
8 mesh to perform with -- under the normal
9 physiologic load, under the normal
10 physiologic capacity, and in that
11 capacity, fraying was not a clinical
12 concern.

13 **Q.** Who told you that these were
14 nonphysiologic forces?

15 **A.** Based upon, you know, my
16 body of knowledge, reading the material,
17 discussing with other experts, you know,
18 having to do a little bit of reading
19 about physiologic forces.

20 I mean, physiologic forces
21 within the pelvic floor, obviously, is
22 somewhat unique to our subspecialty. I
23 don't expect that people are taught that
24 in medical school, for example.

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1 **Q.** So if Ethicon thought --
2 Ethicon thought they were using
3 physiologically forces, you would
4 disagree with them?

5 **A.** I'm sorry?

6 **Q.** If Ethicon, when they did
7 their testing, stated that they were
8 using physiologic circumstances, you
9 would disagree with them?

10 MR. SNELL: Objection to
11 form. Vague.

12 THE WITNESS: I would
13 disagree that they were using
14 phys --

15 BY MS. THOMPSON:

16 **Q.** The amount of stretch, for
17 example? The tension applied, for
18 example?

19 **A.** I mean, the only --

20 MR. SNELL: Same objection.

21 THE WITNESS: I can answer
22 it like this: I am aware that
23 Ethicon conducted testing looking
24 at the mechanical properties of

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1 the mesh and that that testing
2 started from no -- you know, no
3 tension through the physiologic
4 range to supraphysiologic range.

5 It was looked -- it was
6 looked upon -- and this is all
7 kind of -- how the material
8 behaves in that regard, to be
9 honest with you, has very little
10 to do with how the material
11 behaves once it's incorporated or
12 placed within the body.

13 But I know that -- I know
14 that they did perform those tests.
15 I've seen the results of those
16 tests. We have probably, in the
17 past, spoken about data that talks
18 about the different meshes, are
19 they similar -- are they
20 different, similar, physiologic
21 load, supraphysiologic load.
22 Those were all fairly freely
23 discussed.

24 BY MS. THOMPSON:

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1 **Q.** What about roping or curling
2 of the TVT mesh, was that something that
3 was discussed with you prior to your
4 involvement in this lawsuit?

5 **A.** Well, I can -- again, I can
6 tell you, from using that mechanically --
7 mesh for an extended period of time, you
8 know, the mesh does not rope or curl when
9 it's -- when -- you know, in the context
10 that it has a -- the protective sheath
11 over it. And we don't place the mesh
12 without the protective sheath.

13 When the mesh -- so when
14 you're delivering the mesh in the TVT
15 procedure, the sheath is carrying the
16 mesh. The mesh is passive. The mesh is
17 not exposed to the those forces. It's
18 only after the sheath is positioned that
19 you pull the mesh off. Somewhat like the
20 magic trick where you kind of -- not that
21 it's a magic trick, where you pull the
22 table cloth and the stack of cups goes
23 undisturbed.

24 The mesh is never, in the

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1 clinical application of the TVT, as we
2 use it, as I use it for stress
3 incontinence, we don't apply any
4 physiologic force.

5 The only -- the only thing
6 that I would say is that you've got
7 minimal static and rolling friction that
8 does occur as you remove the sheath and
9 the mesh is left behind.

10 Q. So your -- your testimony is
11 that the mesh, if it is placed flat,
12 remains flat?

13 A. Correct.

14 Q. And if Ethicon had evidence
15 to the contrary, is that something that
16 you would like to know about?

17 MR. SNELL: Form.

18 Go ahead.

19 THE WITNESS: It wouldn't
20 hurt my feelings if I was not
21 aware of that information. I
22 don't see how that information is
23 clinically relevant in my world.

24 BY MS. THOMPSON:

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1 **Q.** And would that be the same
2 for other physicians as well?

3 **A.** I can't speak to what other
4 physicians might consider to be relevant.

5 **Q.** If Ethicon had information
6 that the fraying, roping and curling
7 actually increased the risk of retention,
8 is that information that you would like
9 to have?

10 **A.** I -- I would --

11 MR. SNELL: Form.

12 Foundation.

13 THE WITNESS: -- say that I
14 know that information independent
15 of that -- I don't need that
16 information -- okay, Ethicon does
17 not implant these meshes in women.
18 I implant these meshes in women.
19 I implant these meshes in over 100
20 women a year for the past 17
21 years. I am well aware of how
22 this particular material behaves
23 within the body, and I can tell
24 you, when it is done properly,

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1 there is no roping, there is no
2 curling.

3 BY MS. THOMPSON:

4 **Q.** And is that information that
5 other physicians would -- would want to
6 know or need to know from Ethicon?

7 MR. SNELL: Form.

8 THE WITNESS: I would say
9 within the context of the
10 instructions for use, which
11 outlined, in great detail, the
12 very specific steps that are to be
13 taken, when performed in that
14 manner, there is no roping or
15 curling of the material.

16 And keep in mind, we're
17 talking about the tension-free
18 placement of the mesh. So that
19 excludes --

20 BY MS. THOMPSON:

21 **Q.** And you'll agree --

22 **A.** So that excludes all of the
23 testing that you are referring to,
24 because all those testing refer to

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1 tension, whether it's physiologic or
2 nonphysiologic.

3 Q. You'll agree with me that
4 the mesh shrinks, contracts?

5 MR. SNELL: Form.

6 Overbroad.

7 THE WITNESS: As a general
8 sense, a hernia mesh, there is
9 shrinkage. Whether there is
10 shrinkage in a TVT mesh, I don't
11 believe that there is clinically
12 significant shrinkage.

13 Now, of course, because this
14 is the most highly biocompatible
15 mesh there is, it allows for the
16 ingrowth of fibroblasts and
17 reticulocytes. It allows for the
18 infiltration of white cells and
19 angiogenesis.

20 As the tissue heals against
21 the mesh, the mesh is going to
22 change, and that is expected. And
23 that was actually the -- the
24 original design of the TVT

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1 specifically spoke to the fact
2 that the mesh would -- the mesh
3 would induce collagen formation
4 and other structural changes in
5 the area around the mesh. And
6 that was considered to be an
7 important part of the clinical
8 effect.

9 BY MS. THOMPSON:

10 Q. What's your basis for saying
11 TVT is the most highly biocompatible mesh
12 there is?

13 A. I'm sorry. Macroporous
14 polypropylene mesh that is classified as
15 Type I by the Amid classification. Of
16 which --

17 Q. And that's what --

18 A. -- of which --

19 Q. -- you believe TVT is?

20 A. Of which TVT has been the
21 most extensively studied.

22 Q. And you believe that it is?

23 A. I know it is, yes.

24 Q. Despite Ethicon documents

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1 stating otherwise?

2 MR. SNELL: Objection to
3 form. Misstates the evidence.

4 THE WITNESS: My opinion, as
5 an expert, the TVT mesh is Type I,
6 regardless of Ethicon were to tell
7 me yes or no.

8 BY MS. THOMPSON:

9 Q. Okay. If Ethicon had
10 information that showed that the fraying,
11 roping and curling causes the pores to
12 collapse or close and render the mesh no
13 longer macroporous, is that information
14 that you would like to know about?

15 MR. SNELL: Form.
16 Foundation.

17 THE WITNESS: I don't see
18 how it's relevant, counselor,
19 okay?

20 BY MS. THOMPSON:

21 Q. That's -- that's a perfectly
22 acceptable answer.

23 A. As a surgeon, is it -- is it
24 effective.

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1 **Q.** If Ethicon -- and that goes
2 the same for other doctors as well?

3 **A.** I can't speak to what other
4 doctors might hold to be important or
5 what they might comment.

6 **Q.** If Ethicon has information
7 that fraying, roping and curling of their
8 mesh leads to an increased risk of
9 erosion, is that information that you
10 would like to have?

11 MR. SNELL: Form.
12 Foundation.

13 THE WITNESS: I can tell you
14 I have an independent opinion
15 that, yes, if the mesh were to
16 curl, that there might be an
17 increased risk of erosion relative
18 to a mesh that has not curled.

19 Now, the risk of exposure
20 might go from, say, .6 to .7
21 percent, which is what it has been
22 in most clinical trials; maybe
23 that might go up to, say, 1.2, 3
24 percent, 3.2 percent.

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1 But I would agree -- I mean,
2 I would say I have had the same
3 observation, and I don't need to
4 hear that from Ethicon, that if
5 the mesh is not placed in a
6 tension-free manner -- the mesh is
7 not going to rope or curl if it's
8 tension free. Because in it's
9 native state, the mesh is not
10 roped or curled.

11 BY MS. THOMPSON:

12 **Q.** And I think you've already
13 stated that if it's placed flat, in your
14 opinion, it remains flat?

15 **A.** That's correct.

16 **Q.** If Ethicon had information
17 that fraying and roping and curling of
18 mechanically cut mesh leads to an
19 increased risk of bridging fibrosis, is
20 that information you would want to have?

21 MR. SNELL: Form.

22 THE WITNESS: I would --
23 again, bridging fibrosis, in my
24 opinion, is likely to be a natural

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1 or an expected outcome. It's,
2 again, speaking to what the
3 original design -- it was hoped
4 that there would be the induction
5 of collagen, mature collagen
6 formation.

7 And that, yes, I mean, all
8 of these procedures, in the -- in
9 the world of prolapse
10 incontinence, you're kind of
11 hoping that there's a certain
12 degree, again, within a
13 physiologic range, that there's
14 fibrosis, that occurs, absolutely.

15 BY MS. THOMPSON:

16 Q. In other words, replace with
17 scar?

18 MR. SNELL: Form.

19 THE WITNESS: I don't know
20 how it is that you're interpreting
21 scar. I'm talking about the --
22 you want it to induce a certain
23 amount of collagen formation; in a
24 very loose sense scarring, sure.

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1 All surgical procedures result
2 some scarring.

3 Now, whether those -- that
4 scarring occurs from the incision
5 that I've made, whether it occurs
6 from the suture that I've placed,
7 whether it occurs based upon
8 something else I may do, I don't
9 know how I would separate, you
10 know, one from the other.

11 You can -- you will never
12 have no scarring, despite what the
13 TV ads will say. There's no
14 scarless surgery.

15 BY MS. THOMPSON:

16 Q. Do you use polypropylene
17 suture in the vagina?

18 A. Yes.

19 Q. For what procedure?

20 A. Again, the vast majority of
21 what I do in the reconstructive world
22 involves some -- some formulation of
23 polypropylene. Polypropylene sutures are
24 commonly used in all of urogynecology for

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1 apical vaginal suspensions.

2 Q. When you place a
3 polypropylene suture, how much suture is
4 left in the body? What's the length of
5 suture?

6 A. I would say that the length
7 of suture left behind, understanding
8 that, obviously, we've tied a series of
9 knots, I don't know if you're -- you just
10 want -- I mean, the whole thing, in
11 aggregate, is less than a centimeter.

12 If I were to unwind or untie
13 it and stretch it out, that could be,
14 maybe, 3 centimeters. But I don't think
15 that's an accurate -- accurate
16 description. I would say, in general,
17 it's half a centimeter to a centimeter.

18 Q. And do you have any idea how
19 much -- what the length of suture with
20 filaments would be if you stretched out
21 all the polypropylene in a TVT?

22 MR. SNELL: Objection to
23 form.

24 THE WITNESS: I don't have

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1 any -- but, again, keep in mind,
2 all the procedures I'm describing,
3 if I'm doing autologous fascial
4 sling, I'm using very long
5 polypropylene sutures. If I'm
6 doing a Burch suspension, I am
7 using 4 to 6 polypropylene
8 sutures.

9 It's the same.

10 BY MS. THOMPSON:

11 **Q.** So it's your opinion that
12 mesh devices like the TVT and sutures are
13 essentially the same?

14 **A.** No, that's not what I said.
15 I said the polypropylene material is
16 commonly used in urogynecologic surgery.
17 It is the same -- it is the same
18 material -- it's based upon the same base
19 material whether I'm doing an autologous
20 fascial sling, whether I'm doing a Burch
21 suspension, whether I'm doing an vaginal
22 apical suspension, whether I'm doing a
23 synthetic midurethral sling;
24 understanding that when I say synthetic

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1 midurethral sling I am specifically
2 referring to the Retropubic TVT device.

3 Q. Where is the suture placed
4 with an autologous sling?

5 A. Well, the -- there is an
6 autologous -- excuse me, there is a
7 polypropylene suture typically attached
8 at either end of the sling. It is
9 passed, in a similar manner, through a
10 vaginal incision, up through the space of
11 Retzius, up through the rectus fascia
12 into the subcutaneous space, analogous to
13 a TVT procedure. The difference is, it's
14 tied with tension across itself in that
15 manner.

16 Q. But there's no polypropylene
17 underneath the urethra when you do an
18 autologous sling procedure, is there?

19 A. Under the urethra? Well,
20 it's -- unless someone uses a smaller
21 piece of polypropylene to stabilize the
22 mesh under the urethra. And I have seen
23 that.

24 But I would say, you know,

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1 the intended procedure, it's the fascia
2 that is below it.

3 Q. And there's no suture when
4 you are doing a Burch procedure that's
5 placed underneath the urethra, is there?

6 A. Well, the Burch procedure,
7 as I commented earlier, has nothing to do
8 with the urethra. It's a procedure that
9 stabilizes the bladder neck.

10 Now, you know, I -- it just
11 occurred to me that, you know, we have
12 used the material of the sling in the
13 field of urogynecology for probably
14 between 30 and 50 years. You know, it's
15 surprising to me that if the latency for
16 sarcoma is 30 years, we should be seeing
17 those patients. In fact, we should be
18 seeing those patients now.

19 MS. THOMPSON: I don't think
20 there was a question about that,
21 so I'll move to strike that answer
22 as nonresponsive.

23 BY MS. THOMPSON:

24 Q. If Ethicon had information

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1 that the fraying, roping and curling led
2 to a diminished tissue integration, is
3 that information you would want to know?

4 MR. SNELL: Form.
5 Foundation.

6 THE WITNESS: Again, I don't
7 rely upon Ethicon to communicate
8 that information. But I have had
9 discussions with them. I'm
10 aware -- they did communicate that
11 information to myself.

12 BY MS. THOMPSON:

13 Q. And is that information
14 other doctors should or would want to
15 know?

16 A. I can't speak to what other
17 doctors should or would want to know.

18 Q. If Ethicon had information
19 that the fraying, roping and curling of
20 mechanically cut mesh led to an increased
21 risk of infection, is that information
22 you would want to know from Ethicon?

23 MR. SNELL: Form and
24 foundation.

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1 THE WITNESS: Again, I would
2 want to know that information from
3 well-designed, high-level studies,
4 especially -- you know, that's
5 where I would seek that
6 information.

7 I'm sorry, if you're
8 satisfied with that answer, may I
9 take a break to go to the
10 bathroom?

11 MS. THOMPSON: Let me
12 just -- I have about, like, one
13 more question in this section.

14 THE WITNESS: May I be a
15 little more insistent that I be --

16 MS. THOMPSON: Yeah, sure.

17 THE WITNESS: -- allowed to
18 take a break to go to the
19 bathroom?

20 MS. THOMPSON: Yes, sir.

21 VIDEO TECHNICIAN: We are
22 off the record. The time is 6:27
23 p.m.

24 - - -

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1 (Whereupon, a brief recess
2 was taken.)

3 - - -

4 VIDEO TECHNICIAN: We are
5 back on the record. The time is
6 6:40 p.m.

7 BY MS. THOMPSON:

8 Q. Dr. Toggia, had you reviewed
9 the instructions for use for the TVT when
10 you started using the device?

11 A. Yes, absolutely.

12 Q. And did you periodically
13 review the instructions for use as you
14 were teaching courses and acting as a
15 preceptor for Ethicon?

16 A. I did, yes.

17 Q. Do you know whether the
18 instructions for use changed over the
19 time period between 1998 and 2015?

20 A. Yes. My recollection is
21 that part of the work that I did with
22 them, particularly on the TVT EXACT®
23 product, we re-looked at the instructions
24 for use. Certain points were felt that

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1 needed a little bit more emphasis or
2 clarity. There was, maybe, a little bit
3 more specificity in some areas, a little
4 less specificity in other areas.

5 Q. Did the adverse reactions
6 section change at all during that time
7 period?

8 A. I'm not -- I can't give you
9 an independent recollection of that, as
10 we speak. To me, the instructions for
11 use, I focused on, you know, my -- my
12 focus is actually the instructions on
13 using the device.

14 Q. But this -- this document
15 would have been provided to physicians at
16 your training courses, correct?

17 A. I believe so, yes.

18 Q. In your report, I believe,
19 you stated that, IFU is clear, useful and
20 adequate to describe the procedure and
21 potential risks.

22 Does that sound right?

23 MR. SNELL: What page are
24 you on?

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1 MS. THOMPSON: Page 17, at
2 the top of the page.

3 MR. SNELL: Thank you.

4 BY MS. THOMPSON:

5 Q. The IFU and professional
6 education for the TVT are clear, useful
7 and adequate to describe the procedure
8 and potential risks.

9 I'm just reading that from
10 your report.

11 A. I'm sorry, as usual, I'm a
12 little slower than -- than you all.

13 You're saying it's on Page
14 15?

15 Q. I think I said 17.

16 A. Yes.

17 Q. And then -- and you go on to
18 say that, Risks of SUI surgery are
19 obvious to surgeons and as surgeons, we
20 are expected to be aware of the risk in
21 light of our education, training and
22 experience.

23 A. Yes.

24 Q. Do you believe that a

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1 company --

2 MR. SNELL: Let's go off the
3 record.

4 VIDEO TECHNICIAN: We're off
5 the record at 6:43 p.m.

6 - - -

7 (Whereupon, a discussion off
8 the record occurred.)

9 - - -

10 VIDEO TECHNICIAN: We are
11 back on the record.

12 BY MS. THOMPSON:

13 Q. Do you believe, Dr. Toggia,
14 that a company can assume that doctors
15 know certain risks and avoid warning of
16 the risks as a result? That's a
17 yes-or-no question.

18 MR. SNELL: Form. He
19 doesn't have to answer yes or no,
20 he can answer how he sees fit.

21 BY MS. THOMPSON:

22 Q. Do you want me to repeat it?

23 A. Well, I know that -- that
24 this is one of -- you know, as a surgeon

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1 that does anti-incontinence procedure,
2 I'm doing all the other procedures, this
3 is an additional procedure that I'm
4 doing, this procedure is based upon
5 foundation principles that are somewhat
6 common to the other procedures.

7 And so, naturally, it
8 follows that a risk of, say, bladder
9 injury or a risk of bleeding, the risk of
10 infections -- again, these are -- these
11 are inherent risk and elemental risks of
12 all surgical procedures.

13 We're not teaching these
14 procedures to non-surgeons to do. It's
15 not that I'm picking a family practice
16 doctor and saying, here, why don't you do
17 this, you've got some patients.

18 So it's -- I think it's
19 predicated that, you know, a surgeon, you
20 know, that was interested in using a TVT
21 device in lieu of a different procedure
22 that they were presently performing
23 understands the general risks of surgery.
24 I think that's what that statement speaks

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1 to. That was my intention in making that
2 statement.

3 Q. So you're -- you're speaking
4 of the general risk of surgery, not those
5 that are specific to the TVT device?

6 A. I'm talking about the risks
7 that are specific to anti-incontinence
8 procedures in women.

9 MS. THOMPSON: We can stop
10 there.

11 THE WITNESS: No, keep
12 going. That's fine. If you like.

13 MR. SNELL: I'm hungry.

14 MS. THOMPSON: We'll stop.

15 VIDEO TECHNICIAN: We are
16 off the record. The time is --

17 THE WITNESS: That's fine.

18 VIDEO TECHNICIAN: We are
19 off the record at 6:47.

20 - - -

21 (Whereupon, a dinner recess
22 was taken.)

23 - - -

24 VIDEO TECHNICIAN: We are

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1 back on the record. The time is
2 7:24 p.m.

3 BY MS. THOMPSON:

4 Q. Before we get started with
5 the rest of the questions, Dr. Toggia,
6 I've looked through the materials that
7 you've brought.

8 A. Yes.

9 Q. And it looks to me like that
10 top cardboard box has the materials that
11 were not the ones related to your report
12 and the materials that Mr. Snell provided
13 you.

14 MS. THOMPSON: So if we
15 could just mark that box -- the
16 contents of that box as an exhibit
17 for the deposition.

18 MR. SNELL: I don't know if
19 that's accurate, but you can mark
20 whatever you want to.

21 MS. THOMPSON: That was what
22 I kind of determined. Everything
23 else looked like it was either
24 depositions or documents or

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1 literature related to the report.

2 So we'll just do that.

3 MR. SNELL: Well, I did -- I
4 mean, we sent him the depositions
5 after his report and all the
6 exhibits and stuff.

7 MS. THOMPSON: Yeah, but I
8 don't need to mark those.

9 And then did you say that
10 you brought some thumb drives
11 also? I didn't see those.

12 THE WITNESS: It's
13 essentially this -- this material
14 here.

15 MS. THOMPSON: It's
16 basically this stuff, too?

17 THE WITNESS: I can
18 guarantee you it's no different.

19 MS. THOMPSON: Let's mark
20 these.

21 THE WITNESS: One of them is
22 simply -- one of them is simply
23 the expert reports.

24 MS. THOMPSON: So the box

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1 and the two thumb drives.

2 - - -

3 (Whereupon, Exhibit
4 Toggia-9, ETH.MESH 02026591-595,
5 Material Safety Data Sheet, was
6 marked for identification.)

7 - - -

8 (Whereupon, Exhibit
9 Toggia-10, Three Thumb drives
10 produced by Marc Toggia, M.D., was
11 marked for identification.)

12 - - -

13 BY MS. THOMPSON:

14 Q. Dr. Toggia, I think before
15 the break, we were just beginning to talk
16 about the instructions for use.

17 A. Yes.

18 Q. And I believe you said that
19 you reviewed them throughout the time
20 period and up to the present day that
21 you've been using TVT on a -- on some
22 kind of regular basis or --

23 A. TVT and TVT EXACT®.

24 Q. TVT and TVT EXACT®, thank

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1 you.

2 Do you believe that the
3 instructions for use are complete?

4 **A.** I believe that the
5 instructions for use do exactly that,
6 they -- they accurately describe the
7 instructions on how the product is to be
8 used. They provide the step-by-step
9 mechanics of the procedure.

10 **Q.** And complete and accurate in
11 terms of the listing of potential risks
12 as well?

13 **A.** I'm not sure what you mean
14 by "complete." I mean, I think it would
15 be impractical to reissue the instruction
16 for use every week or two. Those are
17 provided inside the box.

18 I don't -- I don't know what
19 form -- you know, what program is used to
20 determine how often to update those.

21 **Q.** Do you know if -- I believe
22 I already asked you the question about
23 how often they were updated. But I can't
24 remember the answer.

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1 **A.** No, you didn't ask me that
2 question.

3 To the best of my knowledge,
4 I'm aware of the initial and then the
5 update that occurred roughly around the
6 time the EXACT® was introduced, I
7 believe.

8 **Q.** And are you aware of an
9 update that occurred some time this year?

10 **A.** I am aware, yes, I did see
11 that. There was an update.

12 - - -

13 (Whereupon, Exhibit
14 Toggia-11, Selection of Materials
15 produced by Marc Toggia, M.D., was
16 marked for identification.)

17 - - -

18 BY MS. THOMPSON:

19 **Q.** I have marked the TVT
20 instructions for use as Exhibit Number 7.
21 And I just have a few questions for you.

22 **A.** This is the original?

23 **Q.** This, I believe, is from --
24 from 2000.

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1 **A.** Please, do not ask me to
2 read anything from this.

3 **Q.** Oh, yeah, I'm sorry about
4 that.

5 **A.** Yeah, in Spanish.

6 **Q.** Let me read -- sorry this
7 the smallness of that print.

8 **A.** I think this is Turkish.

9 **Q.** We're not going to read the
10 Turkish.

11 MR. SNELL: I have 7 marked
12 as the Olmstead clinical thing.
13 And I think you just said this was
14 7.

15 MS. THOMPSON: You know
16 what, we had marked this earlier
17 as 7 and then --

18 MS. COPE: What's the
19 sticker say on it?

20 MS. THOMPSON: The sticker
21 says -- Dr. Toggia, what does the
22 sticker say?

23 THE WITNESS: Mine says 7.

24 MS. THOMPSON: Yeah, we put

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1 a 7 instead, so let's change it to
2 8.

3 - - -

4 (Whereupon, a discussion off
5 the record occurred.)

6 - - -

7 MS. THOMPSON: Off the
8 record till we get our exhibit
9 straight.

10 VIDEO TECHNICIAN: We are
11 off the record. It's 7:30 p.m.

12 - - -

13 (Whereupon, a discussion off
14 the record occurred.)

15 - - -

16 VIDEO TECHNICIAN: We are
17 back on the record.

18 BY MS. THOMPSON:

19 Q. Dr. Toggia, these were how
20 the instructions for use were produced to
21 us, and I apologize for the small print.

22 But I'll read you what I
23 want to ask you about, and if you -- if
24 you can tell at least that it's kind of

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1 close. And we will not be reading the
2 Turkish or Spanish or any other language.

3 On the --

4 A. There's Italian.

5 Q. And Italian. Do you know
6 Italian?

7 A. No.

8 Q. On the second page, Bates
9 number 380, under TVT device, it states,
10 This bidirectional elastic property
11 allows adaptation to various stresses
12 encountered in the body.

13 A. Where do you see that?

14 Q. Under TVT device, the second
15 paragraph, the last sentence.

16 A. And, I'm sorry, this is from
17 when?

18 Q. 2000.

19 A. Okay. I'll accept that.

20 Q. The bidirectional elastic
21 property allows adaptation to various
22 stresses encountered in the body.

23 Do you know what the basis
24 for that statement is?

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1 MR. SNELL: Objection.

2 Completeness.

3 Go ahead.

4 THE WITNESS: I don't know

5 the direct -- what the direct

6 basis is.

7 BY MS. THOMPSON:

8 Q. Would you agree that the

9 bidirectional elastic property allows

10 adaptation to various stresses

11 encountered in the body with the TVT

12 device?

13 A. I would assume that it

14 allows adaptations within two directions,

15 bidirectional.

16 Q. And is it your understanding

17 that that's what the TVT does, how the

18 TVT behaves?

19 MR. SNELL: Form.

20 THE WITNESS: Again, I'm not

21 familiar with the context, so I

22 don't -- can't answer that

23 question, sorry.

24 BY MS. THOMPSON:

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1 **Q.** Did you ever ask Ethicon,
2 during the time that you were serving as
3 a preceptor, what was meant by that
4 statement?

5 **A.** I don't believe I ever asked
6 them what was meant by that statement.

7 **Q.** On the next page, under
8 instructions for use, the first sentence,
9 The procedure can be carried out under
10 local anesthesia, but it can also be
11 performed using regional or general
12 anesthesia.

13 Do you perform most of your
14 TVTs under local or general?

15 **A.** The majority of our
16 procedures, the vast majority, are
17 performed with -- not with general
18 anesthesia. It's local anesthesia with
19 monitored anesthesia care, which is
20 intravenous sedation.

21 There are times, of course,
22 the patient may request general
23 anesthesia. There are times that the
24 anesthesiologist might be insistent on

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1 general anesthesia.

2 I present it as a procedure
3 that we advocate for local with monitored
4 anesthesia care.

5 Q. And with the MAC anesthesia,
6 the patient is asleep, although not under
7 a full general anesthesia, correct?

8 A. As you know, sleep is not a
9 medical term. I would say the patient is
10 not conscious.

11 Q. If Ethicon had information
12 that the success rate was higher if a
13 local anesthesia was used, is that
14 information that you, as a physician,
15 would like to have?

16 MR. SNELL: Form.

17 Foundation.

18 THE WITNESS: I've got to be
19 honest with you, I would not allow
20 Ethicon to -- I mean, I'm the
21 surgeon, I do the procedures, they
22 don't. I don't think the form of
23 anesthesia has any influence.

24 I think that early on we

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1 would talk about whether -- how do
2 you -- how do you set the mesh in
3 its final position, whether you
4 use a, quote/unquote, cough test,
5 which, obviously, you couldn't do
6 with general anesthesia, do you
7 simply eyeball it, use a spacer.

8 I think, really, the
9 underlying message was always that
10 you don't tension -- you don't put
11 tension on the mesh or position
12 the mesh in an obstructive manner.

13 I don't believe, nor am I
14 aware, that the success rates are
15 higher. I don't believe that
16 there are any high-quality studies
17 that randomize people to one or
18 the other.

19 BY MS. THOMPSON:

20 **Q.** Is that information that
21 other physicians would like to have, do
22 you believe?

23 **A.** I know that in the course of
24 training, when I would train a physician,

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1 it's something that we would discuss, you
2 know, as -- as an option.

3 Q. Under adverse reactions,
4 Bates Number 3883 --

5 A. Yes.

6 Q. -- the IFU states,
7 Transitory local irritation at the wound
8 site and a transitory foreign body
9 response may occur. This response could
10 result in extrusion, erosion, fistula
11 formation and inflammation.

12 Is that a correct statement?

13 A. I would assume if it was
14 included in here, that they believe that
15 that was a correct statement.

16 I can't tell you that I
17 personally have ever witnessed any of
18 that.

19 Q. And that's because, of your
20 3,000 patients with pelvic mesh, you've
21 never observed a foreign body response,
22 correct?

23 MR. SNELL: Objection.

24 Misstates.

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1 THE WITNESS: I'm speaking,
2 in this case, specific to the --
3 to the TVT procedure.

4 Again, it's at the wound
5 site, so result of the suture
6 material, cautery, how rough you
7 are with the tissue.

8 I don't -- I don't interpret
9 this as having anything to do with
10 the mesh, per se. I read it
11 literally, which is that there may
12 be local irritation at the wound
13 site and that it is a transient
14 phenomenon.

15 BY MS. THOMPSON:

16 Q. Under actions, the IFU
17 states, Animal studies show that
18 implantation of PROLENE® mesh elicits a
19 minimal inflammatory reaction in tissues,
20 which is transient and is followed by the
21 deposition of a thin fibrous layer of
22 tissue which can grow through the
23 interstices of the mesh, thus
24 incorporating the mesh into adjacent

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1 tissue. The material is not absorbed nor
2 is it subject to degradation or the
3 weakening by the action of tissue
4 enzymes.

5 A. I believe that's an accurate
6 statement, yes.

7 Q. I believe that's all the
8 questions I have on the IFU.

9 MS. THOMPSON: Off the
10 record for a couple minutes,
11 please.

12 VIDEO TECHNICIAN: We are
13 off the record. The time is 7:39
14 p.m.

15 - - -

16 (Whereupon, a discussion off
17 the record occurred.)

18 - - -

19 VIDEO TECHNICIAN: We are
20 back on the record.

21 BY MS. THOMPSON:

22 Q. Dr. Toggia, I'm going to ask
23 you some questions about your work with
24 Ethicon.

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1 Do you remember when you
2 first became a paid consultant for
3 Ethicon?

4 A. As I stated earlier, I do
5 recall, prior to the launch of the
6 product, being part of a focus group in
7 which I was asked to give an opinion on
8 the feasibility of this as a new
9 procedure, and I was paid for that.

10 Q. And we're talking about the
11 TVT in 1998 or 1999, roughly?

12 A. To be honest with you, if I
13 had to give you a guess, this was '96,
14 '97. I'm pretty sure it was '96.

15 Q. And do you recall when you
16 became a proctor for Ethicon?

17 A. I'm going to say 2002,
18 perhaps.

19 Q. And did you have a contract
20 for either of those positions, that
21 you're aware of?

22 A. Well, the focus group, of
23 course, was a single event. The -- at
24 some point in time, there would be a --

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1 there was probably a contract regarding
2 proctoring. And I recall every year
3 that -- that would be a new and usually
4 different terms.

5 **Q.** Do you recall how you were
6 compensated for being a proctor for
7 Ethicon?

8 **A.** Yes.

9 **Q.** How much were you paid?

10 **A.** It depended upon the
11 situation, if I was doing a procedure
12 within my institution, did I have to
13 drive 60 miles, did I get on an airplane.
14 So it would vary.

15 I would -- I would
16 guesstimate maybe \$1,500 at the lower
17 end, \$2,500, maybe \$3,000. You know,
18 sometimes there would be one person, it
19 might be up to three people. There was
20 probably a factor for that.

21 **Q.** So that was per preceptee or
22 group of preceptees that you were paid
23 between \$1,500 and \$5,000?

24 **A.** No \$5,000; \$2,500, \$3,000.

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1 **Q.** \$2,500, I mean.

2 **A.** Again, I think the higher
3 end would speak to more than one. The
4 lower end would speak to location and
5 maybe one. There wasn't that significant
6 of a difference, I don't recall. I mean,
7 the highest might have been \$3,000.

8 They would classify you.

9 Maybe, in the beginning they would call
10 me a local proctor. At some point, I was
11 a national proctor. Physicians might fly
12 in from other locations. I would -- I'm
13 assuming that the reimbursement may have
14 been a little higher. I never did a
15 large volume --

16 **Q.** Do you know --

17 **A.** -- proctoring.

18 **Q.** -- offhand how many doctors
19 that you proctored over the years with
20 Ethicon?

21 **A.** I don't know offhand the
22 number of doctors I proctored. If I were
23 to throw out a term, like, fifteen,
24 twenty over a -- over a ten-year period

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1 of time.

2 And the -- in the context of
3 proctor, I'm talking about a physician
4 that was in the operating room with a
5 patient, not necessarily a lab -- you
6 know, a lab situation, a dry lab
7 situation or anything like that.

8 Q. We have a contract from 2006
9 that says you would be paid a maximum of
10 \$100,000 for the year.

11 Do you recall how much you
12 were actually paid --

13 A. In 2006?

14 Q. -- in 2006?

15 A. In general, it would
16 probably be something like \$12,000, maybe
17 \$15,000.

18 I would say -- I think the
19 highest I had gotten -- and, again, I
20 mean, a total number and this goes
21 beyond -- was maybe \$30,000. But I have
22 to tell you, that probably includes more
23 of the design work that I may have done.

24 Q. So in 2006, your estimation

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1 would be between \$12,000 and \$30,000 that
2 you were paid by Ethicon?

3 **A.** I would say it's probably
4 between \$6,000 and \$20,000. I don't know
5 for sure. It was not, in my estimation,
6 substantial.

7 - - -

8 (Whereupon, Exhibit
9 Toggia-12, ETH.MESH 11843352-364,
10 Consulting Agreement Requisition
11 Form, was marked for
12 identification.)

13 - - -

14 MS. THOMPSON: We have this
15 marked as an exhibit. I only have
16 one copy of the contract. I'm not
17 going to ask any more questions
18 about it, but if you want to look
19 at that, that's fine.

20 BY MS. THOMPSON:

21 **Q.** Do you have records of the
22 money that you received from Ethicon for
23 payment for your services?

24 **A.** As in payment stubs or -- I

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1 haven't done anything with them recently.

2 I mean -- I mean, there may have been one
3 case in 2013. There may have been none
4 for the preceding several years.

5 So, certainly, as we go back
6 five or six years, I don't think I would
7 have -- you know, I would have the
8 original invoices or records, no.

9 Q. When was the last time you
10 proctored a physician for Ethicon?

11 A. To the best of my knowledge,
12 there was one physician that I proctored
13 who was within my system, and I want to
14 say that was maybe 2013. I couldn't -- I
15 mean, to my mind, it seems like it was
16 longer ago than that.

17 Q. Between 2006 and 2013, did
18 you believe that you had a contract each
19 year with Ethicon for various services?

20 A. I believe so. Again, my
21 role with Ethicon changed with time as I
22 looked at different projects or worked on
23 different projects.

24 Q. We have an Excel spreadsheet

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1 that shows \$30,000 in 2011, \$6,000 in
2 2010 and \$15,000 in 2013.

3 Does that sound about right?

4 MR. SNELL: Object to the
5 form. Foundation.

6 THE WITNESS: I believe that
7 that's in the range of the numbers
8 that I had -- that I had
9 recollected.

10 MS. THOMPSON: And we marked
11 that spreadsheet as Exhibit 13, if
12 you want to look at that.

13 THE WITNESS: Sure.

14 - - -

15 (Whereupon, Exhibit
16 Toggia-13, Spreadsheet, was marked
17 for identification.)

18 - - -

19 MR. SNELL: This doesn't
20 have a Bates number on it. Where
21 is it from?

22 MS. COPE: I can get you the
23 number when we print them out.
24 They're not produced, in Excel

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1 format, with a Bates number.

2 MR. SNELL: But it has a
3 Bates number, a document number
4 attached to any native file if
5 it's a produced document --

6 MS. COPE: And what I'm
7 saying is I can get that --

8 MR. SNELL: Oh, you can get
9 that?

10 MS. COPE: -- to you. But
11 when we print it out --

12 MR. SNELL: I got you.

13 THE WITNESS: I'll be honest
14 with you, I can't read any of
15 this. But I'm happy to accept the
16 figures you threw out. But please
17 don't ask me to read the details.

18 I can read my -- I can read
19 my name, I see that, I recognize
20 that.

21 BY MS. THOMPSON:

22 Q. So we don't have time to
23 have you try to read that, correct?

24 Did you ever receive any

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1 gifts from Ethicon or employees of
2 Ethicon?

3 A. Not that I'm aware of, no.

4 Q. Did Ethicon reimburse your
5 travel expenses and travel time while you
6 were working as a consultant for them?

7 A. Yes.

8 Q. And were there times that
9 you also gave presentations at dinner
10 meetings for doctors for Ethicon?

11 A. There might have been. I
12 don't recall that being a common
13 scenario. But I would -- I would
14 venture, yes, there probably were
15 meetings that a presentation -- and,
16 again, I would have trouble separating
17 the TVT stuff from something else.

18 Q. And I believe we have an
19 invoice in 2009 for a \$3,000 speaking
20 stipend for dinner meeting and in 2008,
21 \$3,095.95 for a dinner speaking meeting.

22 Does that sound like that
23 probably happened?

24 A. I'm a pretty cheap date, so

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1 it kind of sounds like something that we
2 might have done.

3 **Q.** \$3,000 for a dinner
4 presentation doesn't sound that cheap to
5 me.

6 **A.** No?

7 **Q.** Does it to you?

8 **A.** Time away from one's family
9 after one has already worked a ten- or
10 twelve-hour day? I'd say that's pretty
11 cheap, but that's just my personal
12 opinion.

13 **Q.** And at those presentations,
14 you would typically show a PowerPoint?

15 **A.** We may have shown a
16 PowerPoint. It could have been more of
17 an informal discussion. I mean,
18 PowerPoints are usually one of my
19 preferred methods to lead a discussion.

20 **Q.** But you don't remember
21 specifically at the dinner meetings that
22 you did for Ethicon whether there was a
23 PowerPoint involved?

24 **A.** I mean, recognizing that

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1 we're in a public restaurant somewhere in
2 Philadelphia, I could see it going either
3 way, based upon the venue.

4 Q. Do you remember preparing
5 slide presentations for any talks at
6 Ethicon?

7 A. I'm sure that I have
8 prepared talks. I don't -- I don't
9 recall.

10 Q. And Ethicon would pay for
11 your travel and meals for those meetings
12 as well?

13 A. They would pay for travel.
14 I'll be very honest with you, I don't
15 usually bill for meals. I have to eat
16 anyhow, that's not usually something I
17 would bill myself.

18 Q. I think we already talked
19 about the clinical study agreements that
20 you had with Ethicon for the TVT.

21 Was there also an agreement
22 for --

23 A. So, I'm sorry, I didn't -- I
24 don't recall I had a study agreement with

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1 Ethicon.

2 What are you referring to?

3 - - -

4 (Whereupon, Exhibit

5 Toggia-14, ETH.MESH 03617772,

6 Consultant Invoice Dated 5/28/09,

7 was marked for identification.)

8 - - -

9 MR. SNELL: What number is
10 this?

11 THE WITNESS: 15.

12 BY MS. THOMPSON:

13 Q. Do you remember an agreement
14 to provide services relating to the
15 PROSIMATM registry?

16 A. This was not a study
17 agreement. I think I -- I just simply
18 read material.

19 PROSIMATM was not a
20 procedure I ever performed or performed
21 clinically. I -- it's a secrecy
22 agreement, which means, I think, they
23 basically talk to me about the procedure.
24 Maybe they had results from a registry

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1 and I was simply reviewing those results.

2 But I did not participate in
3 a PROSIMATM study.

4 Q. Do you remember whether you
5 were paid for whatever service you
6 provided for the PROSIMATM registry?

7 MR. SNELL: Form.

8 THE WITNESS: I'll be very
9 honest with you, I don't recall
10 really having any involvement with
11 PROSIMATM.

12 BY MS. THOMPSON:

13 Q. Why not?

14 A. I don't know. I don't know
15 whether -- whether I was -- it was
16 something that didn't meet my clinical
17 interest, whether they decided that they
18 were not in need of my services.

19 I remember PROSIMATM as a
20 concept. I know there was a clinical
21 trial done. This was not a project that
22 I was active on.

23 Q. And I can't remember from
24 earlier, did you use the PROSIMATM at

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1 all?

2 **A.** No. That's what I'm
3 speaking to.

4 **Q.** In the TVT versus TVT-S
5 study that you participated in --

6 **A.** Yes.

7 **Q.** -- were you paid by
8 Ethicon --

9 **A.** No.

10 **Q.** -- for your participation in
11 that study?

12 **A.** No.

13 **Q.** I believe the disclosure on
14 that article was that you were
15 preceptor -- preceptor for Ethicon at the
16 time the paper was published?

17 **A.** Yes, that would be a
18 separate.

19 **Q.** Was that the full extent of
20 your employment with Ethicon?

21 MR. SNELL: Objection.

22 Form. He wasn't employed by
23 Ethicon.

24 MS. THOMPSON: Sorry, my

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1 fault.

2 BY MS. THOMPSON:

3 **Q.** Your financial arrangement
4 with Ethicon?

5 **A.** I'm sure you understand that
6 the publication occurred years after the
7 actual study was completed. I would
8 think that the disclosure came at the
9 time of submission of the manuscript for
10 publication. So it wasn't during the
11 study.

12 I mean, I think that my
13 relationship with Ethicon was fairly
14 consistent over those -- over that
15 ten-year period of time.

16 So I have no reason to -- I
17 hope you understand the differential I'm
18 trying to make, because I'm trying to be
19 accurate.

20 I assume that I was -- I was
21 a preceptor at the same time -- I mean, I
22 trained some of the -- I trained some of
23 the other investigators in the trial.
24 I'm -- I pretty strongly don't think

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1 there was -- I charged -- Ethicon did not
2 pay me for any of that nor did they
3 reimburse me for travel. That's just
4 something that I did because these were
5 my colleagues, if that makes sense to
6 you.

7 **Q.** Sure. And how many times
8 did you do cadaver labs for Ethicon,
9 ballpark?

10 **A.** It could be four. It could
11 be eight. I would say maybe closer to
12 the four.

13 **Q.** For what products did you do
14 cadaver labs?

15 **A.** You know, oftentimes,
16 because cadaver labs are so expensive to
17 obtain the materials, it certainly was
18 typical that on one day we might have
19 been working with TVT-Secur, we might
20 have been working with PROLIFT®, we might
21 have been -- I'm sure that we worked with
22 Retropubic and Obturator.

23 **Q.** Did I ask you how many
24 PROLIFT® devices you actually placed?

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1 **A.** You have not asked me that.

2 **Q.** I didn't think so.

3 Could I ask you that
4 question, how many PROLIFT® devices did
5 you actually place?

6 **A.** You know, according to the
7 information that I just sort of tracked
8 upstairs here, it was probably in the
9 vicinity of about 400.

10 **Q.** And when did you stop using
11 PROLIFT®?

12 **A.** Once it was removed from the
13 market.

14 **Q.** Are you aware that your
15 website still includes PROLIFT® as an
16 option for women who have prolapse?

17 **A.** I am aware. And if I had
18 the time or the knowledge to remove it, I
19 certainly would. But thank you for
20 reminding me of that outdated
21 information.

22 **Q.** You're welcome.

23 Did Ethicon also help you
24 advertise your practice?

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1 **A.** There was a brief window of
2 time that Ethicon, in professional
3 education, was interested in helping to
4 raise awareness of pelvic floor
5 dysfunction and the treatments for that.

6 My -- I only -- I only
7 remember one situation in which we placed
8 an ad in a magazine. I think it
9 corresponded to when I had hired a new
10 partner, and I just was interested in
11 letting people know that our practice had
12 these two physicians.

13 I don't think that that ran
14 for more than three months. That's my
15 only recollection. It was kind of a, you
16 know, what do you think of this idea, you
17 know. I think we just -- we did it on a
18 one-time basis.

19 **Q.** But in addition to the money
20 that you were paid by Ethicon for various
21 preceptor trips, dinner presentations, et
22 cetera, they did provide advertisement
23 for your practice?

24 MR. SNELL: Objection to

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1 form.

2 THE WITNESS: In a sense. I
3 mean, it's not that they paid me
4 and I paid for the ad. Like, with
5 the clinical trials, I didn't get
6 the money, the money was -- would
7 have been -- would go through our
8 channels, that's what the Lankenau
9 Institute of Medical Research
10 does; I believe that they may have
11 been involved with the clinical.

12 So the money went somewhere.
13 It's not -- not money that I
14 touched, so to speak.

15 BY MS. THOMPSON:

16 Q. Going back to something you
17 mentioned a minute ago.

18 What information did you
19 just check upstairs?

20 A. I checked in with my wife
21 upstairs, and I looked over my report.

22 Q. You mentioned that you,
23 after checking the information upstairs,
24 you thought that you had done about 400

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1 PROLIFT® procedures, that's what I was
2 asking about.

3 A. Oh, excuse me --

4 MR. SNELL: That's in his
5 head.

6 THE WITNESS: It's just --

7 MS. THOMPSON: Oh, I took
8 it --

9 THE WITNESS: No, no. I'm
10 so sorry.

11 MS. THOMPSON: Oh, I took it
12 literally.

13 THE WITNESS: No, no.

14 MS. THOMPSON: I'm glad we
15 clarified that.

16 MR. SNELL: That was taken
17 out of context.

18 THE WITNESS: My apologies.

19 BY MS. THOMPSON:

20 Q. Dr. Toggia, did you ever
21 complain to Ethicon that its business
22 practices affected the income received by
23 your practice?

24 A. Oh, I'm sure that I may

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1 have, in frustration, made comments.

2 I've got to be honest with you, I don't
3 think it helped or hurt in a significant
4 sense.

5 But, occasionally, I
6 might -- might have gotten my feelings,
7 you know, hurt.

8 Q. Do you remember sending an
9 e-mail to someone at Ethicon about lost
10 business as a result of some of the sales
11 reps activities, Eileen's specifically?

12 A. I don't. I'm aware of an
13 e-mail, I don't -- can't tell you that I
14 remember, at the time, again, sort of the
15 context.

16 But, yeah, there was --
17 there was a point that I was a little
18 grumpy about things. Although I may have
19 been simply misdirecting my frustration
20 in the wrong direction, more than likely.

21 Q. And was that because they
22 had trained one of your referral
23 physicians who then became a competing
24 physician?

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1 **A.** I mean, this is referring to
2 Dr. Finnegan. Dr. Finnegan is a
3 colleague of mine.

4 I don't -- I see the
5 statement. I understand what that seems
6 to be. I can't tell you that I ever felt
7 like that that hurt my business. I
8 think, really, what I -- the message that
9 I was trying to do here -- the message I
10 was trying to get across here, which I
11 will tell you, at this point, I was
12 completely ineffective, I was simply
13 trying to say, look, if we're going to
14 train physicians, you know, within my
15 department, I would like to be the
16 trainer, in that I would like to have a
17 relationship with people, so if they're
18 doing these procedures and they want
19 advice, I would like to be viewed as --
20 as someone they could speak to.

21 And I think that's really
22 what I was trying to get at, although, I
23 admit, I did not state it -- I did not
24 state it well.

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1 And, to be honest with you,
2 I was being a bit dramatic here. I have
3 a very cordial relationship with
4 Finnegan. I don't think he's had any
5 effect on my business whatsoever.

6 - - -

7 (Whereupon, Exhibit
8 Toggia-15, ETH.MESH 10399348,
9 4/29/09 E-mail from Patricia Beach
10 to Judi Gauld; Subject: FW:
11 PROSIMATM Registry, was marked for
12 identification.)

13 - - -

14 BY MS. THOMPSON:

15 **Q.** Did Ethicon pay for
16 community education or other events that
17 may have resulted in increased patients
18 or business for you?

19 **A.** It was not uncommon -- when
20 you say "paid for," let me, please, just
21 sort of qualify that.

22 So we would -- from time to
23 time, we would give community education
24 events on the hospital campus. The

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1 company would provide snacks and
2 refreshments. I don't think that there
3 was ever a situation where I was paid to
4 give that presentation. The
5 presentations, typically, were general
6 presentations; I'm going to talk to you
7 about incontinence, whether that be urge
8 incontinent, whether that be stress
9 incontinence; I'm going to talk to you
10 about prolapse.

11 Does that make sense? But I
12 don't think I was ever paid -- I was
13 never financially rewarded for that.
14 They simply provided snacks and
15 refreshments in that regard.

16 Q. Are there -- are any of the
17 awards or recognitions that you received
18 the result of nominations from Ethicon?

19 A. No, not that I'm -- no. I
20 was never a high priority for them, to be
21 honest with you, given that, you know, we
22 had very well known -- other consultants,
23 I'm sure you must be aware, within a
24 short distance from here. I was kind of

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1 like -- in that regard, no.

2 **Q.** Do any of the committees or
3 organizations or employers have policies
4 regarding conflict of interest or
5 accepting money from industry sources?

6 **A.** You're talking --

7 MR. SNELL: Form.

8 THE WITNESS: You're talking
9 about my employment?

10 BY MS. THOMPSON:

11 **Q.** Yes.

12 **A.** So my employment contracts
13 do have language that allows me to
14 function as a consultant to industry, to
15 publish articles, books, where I might
16 get a royalty.

17 **Q.** And the academic
18 institutions with which you're affiliated
19 don't have policies regarding accepting
20 payments from industry?

21 **A.** Not as they affect me, since
22 I'm not -- you know, that's usually the
23 case if that's the person who is paying
24 your salary.

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1 I think it really -- those
2 kind of relationships say, look, you
3 can't sort of double dip. You can't
4 be -- you can't be getting paid as a
5 physician and, simultaneously, at that
6 same time.

7 Q. Have you disclosed your
8 financial relationship with Ethicon to
9 committees that you've served on, for
10 example, AUGS?

11 A. Of course. We're very
12 transparent. I mean, the public is
13 aware. I mean, you've got The Sunshine
14 Act. There are -- there -- certainly
15 it's public knowledge.

16 It's also public knowledge
17 what, you know, CMS has paid me, which is
18 Medicare.

19 Q. And you've disclosed your
20 conflict of interest with Ethicon on all
21 your publications since the time that you
22 began working for Ethicon?

23 MR. SNELL: Form.

24 THE WITNESS: I don't work

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1 for -- I never worked for Ethicon.

2 I don't --

3 BY MS. THOMPSON:

4 Q. Doing work for Ethicon?

5 MR. SNELL: Same objection.

6 THE WITNESS: I have done --

7 I have done contractual work with

8 Ethicon. I don't know what I -- I

9 don't have any responsibility to

10 report to them what I publish or

11 what else that I do.

12 BY MS. THOMPSON:

13 Q. Do you disclose the work

14 that you do with Ethicon to residents

15 that you're teaching?

16 A. Yes.

17 Q. Has Ethicon ever asked you

18 to attend society meetings and give

19 presentations or be represented at

20 exhibitions at the society meeting?

21 A. I don't believe I've ever

22 done anything like that for Ethicon.

23 Q. Dr. Toggia, did you have a

24 sexual relationship with Kathleen Feeney?

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1 **A.** No.

2 MR. SNELL: Objection.

3 BY MS. THOMPSON:

4 **Q.** Did you have an affair with
5 Kathleen Feeney?

6 MR. SNELL: Same objection.

7 THE WITNESS: I don't know
8 what you're referring to.

9 BY MS. THOMPSON:

10 **Q.** Did you have anything other
11 than a professional relationship with
12 her?

13 MR. SNELL: Same objection.
14 Argumentative.

15 THE WITNESS: You know, I
16 mean -- you know, we were friends,
17 in a sense, although it's not a
18 friendship that extended beyond,
19 like, when she left the company.
20 It quickly, you know -- I don't
21 know where you're coming from.
22 This -- Kathleen Feeney is --

23 - - -

24 (Whereupon, Exhibit

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1 Toggia-16, ETH.MESH 11838868-869,
2 5/30/07 E-mail from Kathleen
3 Feeney to Cindy Pypcznski;
4 Subject: FW: Surgery at Lankenau,
5 was marked for identification.)

6 - - -

7 BY MS. THOMPSON:

8 Q. Did you -- did you -- do you
9 recall an e-mail when she was leaving the
10 company in which she provided you with
11 her personal e-mail address?

12 A. I know that Kathleen Feeney
13 was interested in me, perhaps, writing a
14 letter of recommendation. I know that
15 she had asked me could she have -- could
16 I be a reference, and in that context
17 there may have been.

18 Q. Do you remember asking her
19 what she would use as her name when she
20 left Ethicon. And she said -- replied
21 Kath Toggia?

22 A. I -- Kathleen would make
23 offhanded comments from time to time. I
24 can't say I can't remember her ever

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1 saying that. But I wouldn't be
2 surprised. She was teasing me at the
3 time, of course.

4 MS. THOMPSON: I think
5 that's all the questions I have
6 for you. Thank you, Dr. Toggia,
7 for your time.

8 MS. COPE: Sorry, just
9 wanted to clarify. That one
10 document that didn't have the
11 Bates number, I got the Bates
12 number, if you want to stick that
13 on the exhibit.

14 MR. SNELL: Let's go off the
15 record.

16 VIDEO TECHNICIAN: We are
17 off the record. The time is 8:10
18 p.m.

19 - - -

20 (Whereupon, a brief recess
21 was taken.)

22 - - -

23 VIDEO TECHNICIAN: This
24 marks the beginning of Video

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1 Number 5. We are back on the
2 record. The time is 8:17 p.m.

3 - - -

4 EXAMINATION

5 - - -

6 BY MR. SNELL:

7 **Q.** Dr. Toggia, we're back. I
8 just have a few follow-up questions,
9 following up on plaintiffs' counsel's
10 questions to you.

11 First of all, I believe you
12 were trying to explain your methodology
13 to plaintiffs' counsel.

14 Can you state your
15 methodology that you utilized in
16 assessing the utility and the safety of
17 the TVT device for its intended use to
18 treat stress urinary incontinence?

19 **A.** Yes. So the question that
20 was put before me is whether or not the
21 TVT was well suited for its intended
22 purpose, which was the treatment of
23 stress urinary incontinence in women,
24 whether or not that -- it achieved that

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1 intended use, whether or not that was --
2 the device was safe for that use.

3 In order to formulate that
4 opinion, I reviewed the highest levels of
5 evidence that I could find. As I stated
6 earlier, the highest levels of evidence
7 would include things like randomized
8 control trials, systematic reviews or
9 meta-analysis and, fortunately, there was
10 a tremendous amount of data.

11 Just right behind that would
12 be things like long-term registry
13 studies, the data that came from closed
14 health systems and the like.

15 I would add that the
16 societal guidelines position statements,
17 which are -- in essence, is a different
18 type of a committee that would have done
19 their own systematic review and then
20 formulated an opinion in the same manner.
21 Those are the type of things that I would
22 look at myself.

23 In addition, I looked at the
24 documents provided to me concerning the

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1 internal Ethicon communications. I
2 looked at some of the -- the expert
3 opinions provided by the plaintiffs'
4 side. We looked at, you know, animal
5 studies, in vitro studies. Although,
6 again, recognizing that those are really
7 Level 5 evidence data, that you really
8 can't draw any clinical inference or --
9 or application directly to the TVT
10 device. Those were looked at as well.

11 Q. You saw that plaintiffs'
12 experts cited to a bunch of hernia
13 documents, prolapse documents, animal
14 studies in their reports?

15 A. Yes, I saw that. Yes.

16 Q. And I believe you earlier
17 told plaintiffs' counsel you were shocked
18 at their methodology; is that accurate?

19 A. I would -- I would --

20 MS. THOMPSON: Object to
21 form.

22 THE WITNESS: I was -- I did
23 not find their methodology to be
24 scientifically rigorous. They did

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1 not seem to include the Level 1
2 studies, randomized control
3 trials. They did not refer to the
4 systematic reviews.

5 Their focus seemed to be
6 largely on very low-level, almost
7 insignificant things that really
8 had no direct application to the
9 TVT design, safety or the device
10 when it's used in its intended
11 manner to treat stress urinary
12 incontinence.

13 BY MR. SNELL:

14 Q. So for these hernia
15 documents or hernia studies that the
16 plaintiffs' experts, like Dr. Elliott,
17 seem to cite on every page of his report,
18 would those even fit on the evidence
19 pyramid, if one was to do a proper
20 methodologic scientific review to assess
21 the safety of TVT for its intended use to
22 treat stress urinary incontinence?

23 MS. THOMPSON: Object to
24 form.

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1 THE WITNESS: Within the --
2 within the context, those would
3 not figure as well. Those would
4 usually be discarded as being not
5 relevant to the TVT sling, the
6 device or its design.

7 BY MR. SNELL:

8 Q. You brought these evidence
9 pyramids.

10 MR. SNELL: I'd like to mark
11 them as exhibits.

12 - - -

13 (Whereupon, Exhibit
14 Toggia-17, Level of Evidence
15 Chart, was marked for
16 identification.)

17 - - -

18 (Whereupon, Exhibit
19 Toggia-18, Level of Evidence
20 Pyramid, was marked for
21 identification.)

22 - - -

23 BY MR. SNELL:

24 Q. Doctor, Exhibits 17 and 18,

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1 are those the level of evidence pyramids
2 you brought?

3 **A.** Yes.

4 **Q.** Are those important in
5 conducting a proper -- strike that.

6 Is utilizing the highest
7 levels of evidence important in assessing
8 the question, is the TVT reasonably safe
9 for its intended use to treat stress
10 urinary incontinence, in your opinion?

11 **A.** Absolutely. I mean, the
12 foundation of any systematic review is to
13 start with your highest level of
14 evidence. If you have the highest level
15 of evidence, then the lower levels of
16 evidence typically are not given weight.

17 Certainly if they are
18 incongruent -- if the lower evidence --
19 levels of evidence are incongruent with
20 the higher levels of evidence, it just
21 simply validates and verifies the
22 uselessness of those articles.

23 **Q.** And I believe you testified
24 your methodology was to look at the

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1 highest levels of evidence --

2 **A.** Of course.

3 **Q.** -- and not just one

4 document -- strike that.

5 Not just one guideline or

6 randomized control trial but numerous

7 ones?

8 **A.** We looked for consistency of

9 the levels of evidence -- excuse me, we

10 looked for consistency of the independent

11 analyses that had similar levels of

12 evidence.

13 **Q.** And did you find consistency

14 in the systematic reviews and

15 meta-analyses that were Level 1 evidence,

16 such as the shunt 2014 SGS study or paper

17 and the AUA guidelines that did a

18 systematic review?

19 **A.** They're all very consistent

20 speaking to the safety -- long-term

21 safety, long-term effectiveness of that

22 device.

23 **Q.** On Page 18 of your report,

24 you talk about the safety and surgical

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1 re-intervention being well studied,
2 utilizing national and regional closed
3 systems.

4 Do you see that at the top?

5 **A.** Yes, I do.

6 **Q.** That's something you were
7 talking to the plaintiffs' counsel about,
8 the significance of the closed systems.

9 Do you recall that?

10 **A.** Yes, I -- I started to
11 discuss that. And the point I was trying
12 to make is that the advantage of the --
13 you know, certainly one of the concerns
14 about following patients or looking for
15 complications is, what's your degree of
16 follow-up and whether or not those
17 patients are somehow excluded. That's
18 where concerns that relate to things like
19 selection bias could come from.

20 The advantage of looking at
21 data, whether it's Medicare data, like
22 the Thomson Reuters MarketScan data,
23 Kaiser, Canada, some of the other
24 countries, is that people, you know,

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1 don't drop out of the system and they are
2 able to capture, with a high degree of
3 accuracy, what happens to these
4 individuals over time.

5 Q. And in Pages 17 through 21,
6 do you identify some of those studies
7 that you reviewed and found to be
8 scientifically reliable and high levels
9 of evidence?

10 A. Yes, they are -- and they
11 are consistent with the Level 1 data and
12 the systematic reviews.

13 Q. Earlier, plaintiffs' counsel
14 asked you some questions about the AUGS
15 position statement.

16 Do you recall that in
17 general?

18 A. Yes.

19 Q. Can you turn to that? I
20 just have a few follow-up questions. I
21 believe it was in one of these multiple
22 binders.

23 A. Less than one minute, sir, I
24 have it right in front of me.

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1 Oh, I have to apologize.

2 Okay.

3 Q. Remember plaintiffs' counsel
4 asked you some questions about the
5 AUGS/SUFU position statement and whether
6 it had any discussion about safety or
7 complications?

8 A. Yes.

9 Q. Take a look at Paragraph
10 Number 2.

11 Does the AUGS/SUFU statement
12 have any discussion about an assessment
13 of whether the TVT or midurethral sling
14 is safe?

15 Sorry, numbered Paragraph 2,
16 unless I'm --

17 A. Numbered paragraph. Oh, I'm
18 sorry.

19 Number 2 which starts, The
20 monofilament polypropylene mesh is the
21 most extensively studied
22 anti-incontinence procedure in history.

23 So, yes, this particular
24 paragraph -- and the references are

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1 provided, and I would point out that the
2 references cited do consist of
3 high-quality levels of evidence, which
4 talks about the fact that -- that this
5 particular procedure had been studied as
6 long in follow up than any other
7 procedure and seems to demonstrate
8 superior safety and efficacy.

9 Q. If you look at Reference
10 Number 8, under Paragraph 1, where it
11 talks about the lightweight monofilament
12 polypropylene sling has demonstrated
13 long-term durability, safety and efficacy
14 for up to 17 years, are they referring to
15 the Ethicon TVT Retropubic sling that
16 assessed?

17 A. Yes. That refers to the
18 Nielsen long-term prospective cohort
19 that, I believe, looked at, over a
20 17-year period of time, a group of
21 approximately 90 individuals.

22 Q. Does that AUGS/SUFU position
23 statement, is it reliant upon Level 1
24 evidence like Cochrane reviews or

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1 randomized control trials?

2 A. Yes, it is.

3 Q. One of the end notes in the
4 overall assessment of the slings is
5 Cochrane review by Ogah, et al.

6 A. Yes.

7 Q. Is that a study that you're
8 familiar with?

9 A. It is. But that's a
10 meta-analysis.

11 Q. And what is the significance
12 of that type of meta-analysis and being a
13 Cochrane review, if anything?

14 A. Sure. So a meta-analysis
15 seeks to look at as much of the relevant
16 literature. As well, it will -- it will
17 take all of the randomized control
18 trials, it will sort of combine the data,
19 in a sense, for analysis. It will draw
20 comparisons to the other procedures or
21 the other approaches.

22 Q. Okay. And do those
23 references that the AUGS/SUFU position
24 statement rely upon for the statements in

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1 that assess the complications with TVT?

2 A. Yes.

3 Q. Such that -- and I believe
4 you talk about, in the Ogah study, in
5 your report, you discuss that that
6 Cochrane review discusses multiple
7 complications?

8 A. It does.

9 Q. Including that the
10 monofilament and macroporous mesh, like
11 TVT Retropubic, in the treatment of
12 stress urinary incontinence has a lower
13 rate of exposure than the multifilament
14 meshes.

15 Do you recall that from the
16 Ogah Cochrane review?

17 A. Yes. And I believe that the
18 majority of the studies that were
19 included in that analyses would have been
20 specifically with the Retropubic TVT
21 device.

22 Although, there was another
23 part of the analysis that would have
24 looked at the Obturator approach as

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1 compared to the Retropubic approach.

2 Q. Considering that this
3 AUGS/SUFU position statement, as you have
4 testified, relies on Level 1 systematic
5 reviews and other data, do you believe it
6 is reliable?

7 A. Absolutely.

8 Q. Some questions were asked to
9 you -- strike that.

10 And do you believe that the
11 other position statements and the stress
12 urinary incontinence systematic reviews
13 and guidelines by SGS, the American
14 Urologic Association, IUGA, and others,
15 are also reliable?

16 A. They are -- they are
17 reliable and they're incredibly
18 consistent with each other.

19 Q. You were asked some
20 questions about complications your
21 patients may have had and how plaintiffs'
22 counsel, what documents she would go
23 to --

24 A. Sure.

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1 **Q.** -- to look for that.

2 My question to you is this:

3 Did you track your patients' complication
4 rates over time with the TVT Retropubic
5 device?

6 **A.** Yes, we did.

7 **Q.** How did you do that?

8 **A.** We kept notes on the
9 patients. I mean, most -- you know, when
10 you're dealing with a procedure that, in
11 our hands, had complication rates in the
12 single digits, it's not that hard to make
13 the mental note, you know, that, you
14 know, we saw two episodes of bleeding
15 that required observation.

16 **Q.** Did you counsel your
17 patients on your rates of complications
18 you had with the TVT Retropubic device
19 over time as you gained experience?

20 **A.** Yes. I felt an obligation,
21 certainly, as somebody that was well
22 respected in this field and somebody that
23 was able to offer several different
24 options to my patients in this, that we

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1 would talk to them, again, sort of about
2 our personal experience.

3 You know, when you -- when
4 you work out in the community and you
5 take care of women in the community and
6 you're not necessarily at a university
7 hospital, I have found that women are
8 very much interested in what your
9 personal experience was.

10 Obviously, we were very
11 fortunate to have a high volume of cases.
12 And within that context, I could say to
13 them, you know, regularly, look, I've
14 done 500 of these and, you know, the
15 complications that we have seen are --
16 you know, there have been occasional
17 episodes of bleeding from time to time,
18 either during or after the procedure,
19 things of that nature.

20 Q. And so when you put in your
21 report, for example, your complication
22 rates, in your hands and -- for example,
23 that your rate of bladder perforation
24 with the TVT Retropubic decreased over

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1 time as you became more experienced, are
2 those reliable rates?

3 A. Yes.

4 Q. Are those based on your
5 firsthand observations and tracking of
6 your complication rates over time with
7 the TVT Retropubic device?

8 A. They are.

9 Q. You talked to plaintiffs'
10 counsel about your various different
11 design expertise and work you did with
12 Ethicon on many different products.

13 Do you recall that?

14 A. I do.

15 Q. One thing I want to ask you
16 about, I didn't recall if you said it or
17 not, but do you recall the GYNEMESH® M,
18 the ULTRAPRO™ mesh product that was used
19 in PROLIFT®?

20 A. I do.

21 Q. Do you recall --

22 A. That was used, excuse me, in
23 PROLIFT® +M.

24 Q. PROLIFT® +M. Thank you for

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1 your correction.

2 A. Sure.

3 Q. Do you recall that you were
4 actually one of the surgeons that did the
5 design validation of the GYNEMESH® M
6 mesh, assessing the suitability, safety
7 and efficacy and adequacy of that design?

8 A. I did participate in some
9 kind of a design validation study, yes.

10 Q. Do you recall assessing the
11 IFU for that device during the design
12 validation?

13 A. Yes, I do.

14 Q. And whether you were asked,
15 is the IFU, clear, cohesive, accurate, do
16 you recall that?

17 A. Yes.

18 Q. And did you give opinions to
19 Ethicon in that design validation for the
20 GYNEMESH® M device?

21 A. I provided them with, you
22 know, constructive feedback.

23 Q. Some questions were asked of
24 you, I think, about pubovaginal sling

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1 exposures or wound complications with the
2 Burch.

3 I want to hand you the
4 Schimpf paper.

5 And, actually, first of all,
6 do you have your report handy?

7 **A.** I do.

8 **Q.** Turn to Page 19, on the
9 second paragraph, where you discuss wound
10 complications occurring with the Burch
11 and autologous fascial sling.

12 Do you see that?

13 **A.** The -- you're referring to
14 Novara, et al.?

15 **Q.** I'm right here on Page 19?

16 **A.** I'm sorry. Yes.

17 **Q.** So in the Schimpf -- I put
18 before you the Schimpf SGS systematic
19 review and meta-analysis.

20 Is that a document you're
21 familiar with?

22 **A.** Yes, it is.

23 **Q.** Is that a document you
24 reviewed and rely upon?

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1 **A.** Yes, it is.

2 **Q.** Is that a document that's
3 reliable, in your opinion, to
4 scientifically assess the safety and
5 utility of the design of the TVT
6 Retropubic device?

7 **A.** It's a very reliable
8 device -- very reliable document.

9 This is what -- this is what
10 we were speaking to Level 1 evidence.
11 This is a systematic review -- an
12 independent systematic review.

13 **Q.** And the Society of
14 Gynecologic Surgeons, do they have a good
15 reputation within the field of female
16 pelvic medicine?

17 **A.** Absolutely.

18 **Q.** Do you actually belong to
19 that society?

20 **A.** I serve a leadership role.
21 I serve on the executive committee for
22 that society.

23 **Q.** And in your role and
24 participation with the society -- let me

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1 ask you this: Before I contacted you and
2 asked you to analyze the data, had you
3 already been reviewing and analyzing data
4 on the TVT Retropubic device?

5 A. Yes.

6 Q. Had you been reviewing data
7 and analyzing data, the different levels
8 of data, on the TVT Retropubic device
9 going back all the way to when you began
10 considering to use it?

11 A. Yes. Absolutely.

12 Q. So let's look at the Schimpf
13 systematic review and meta-analysis.

14 Does that study -- strike
15 that.

16 Looking at the Schimpf
17 systematic review -- review and
18 meta-analysis, does that Level 1
19 systematic review inform you of wound
20 complications and other problems that can
21 occur with the Burch and the pubovaginal
22 sling?

23 A. It does.

24 Q. In the table in the Schimpf

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1 paper, does it identify whether patients
2 with pubovaginal sling or Burch have
3 wound infections, exposure and return to
4 the operating room for erosions?

5 **A.** Yes. Table 3, specifically,
6 addresses the analysis that would look
7 at -- and, again, this was exclusive
8 of -- excuse me, this was inclusive of
9 randomized control trials.

10 So this is a -- this is a
11 summary of the analysis of Level 1 data.

12 **Q.** And did the Schimpf
13 systematic review, the summary of Level 1
14 data, identify that the Burch and the
15 pubovaginal sling had exposures or return
16 to the operating room for erosion?

17 **A.** Yes.

18 **Q.** Did -- go ahead. I'm sorry.

19 **A.** So, specifically, it
20 analyzed the number of studies and the
21 incidence of, say, exposure between three
22 different types of midurethral slings,
23 the traditional, pubovaginal vaginal and
24 the Burch.

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1 It also looked at return to
2 the operating room specifically to
3 treat -- to treat erosions as well. It
4 looked at wound infections, hematoma,
5 dyspareunia, various organ injuries.

6 **Q.** Did -- did that inform your
7 opinions on the safety of the TVT device
8 for the intended use of the treatment of
9 stress urinary incontinence?

10 **A.** Yes. And, obviously, as you
11 can imagine, I was very reassured by the
12 fact that it was both consistent with my
13 experience, having performed, you know,
14 each of these procedures, and also
15 confirmed my experience and my own review
16 of the literature of the safety and
17 long-term efficacy of this procedure.

18 **Q.** You mentioned earlier that
19 there was consistency in the Level 1 data
20 and the longer-term studies, the
21 prospective database studies.

22 Why is that important in
23 conducting a proper scientific
24 methodologic analysis of the question, is

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1 the TVT safe for its intended use to
2 treat stress urinary incontinence?

3 **A.** Well, objectivity. You
4 know, the reasons why one designs a
5 randomized control trial is that we're
6 trying to eliminate everything from
7 selection bias, having patients that
8 might be sicker in one arm versus the
9 other, more comorbid conditions,
10 variations that might relate individually
11 to a certain -- a particular surgeon or
12 institution.

13 **Q.** Plaintiffs' counsel asked
14 you about degradation, and I believe you
15 told her, numerous times, that you didn't
16 believe that the TVT degraded; is that
17 correct or not?

18 **A.** Within the clinical use of
19 the TVT for the treatment of stress
20 urinary incontinence, there -- I'm not
21 aware of any reliable data suggesting
22 that there is degradation.

23 **Q.** The plaintiffs' counsel
24 asked you a question about were there any

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1 studies that -- I think the question was,
2 and it may have been a double negative --
3 that did not show oxidative degradation.

4 Do you recall questioning on
5 that?

6 A. I do. And the more that I
7 thought about it, I realized that I did
8 address that in my report.

9 Q. Can you turn to Page 26 of
10 your report?

11 A. Yes.

12 Q. There was a paper that the
13 plaintiffs' experts pointed to by Clave.

14 Do you -- have you read that
15 paper?

16 A. I'm familiar with that
17 study.

18 Q. And, first of all, is that
19 study a reliable study to assess,
20 scientifically, the TVT and, in
21 particular, for its intended use to treat
22 stress urinary incontinence?

23 A. I mean, I don't believe that
24 the Clave study looked specifically at

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1 the TVT device, per se. So it was a
2 low-level observational study, in vitro,
3 in a sense, in that the -- in that the
4 material was analyzed under a scanning
5 electron microgram and some chemical
6 analysis.

7 Q. And I believe you earlier
8 testified, for the intended use of
9 treating stress urinary incontinence, is
10 Clave one of the studies that wouldn't
11 even make it onto the level of evidence
12 pyramid because it doesn't specifically
13 focus on the intended treatment of stress
14 incontinence?

15 A. I don't believe that Clave
16 would be considered in that kind of
17 high-level evidence analysis, in terms of
18 the clinical utility, safety or design of
19 that device.

20 Q. So back to my earlier -- the
21 reason why I brought you to this study or
22 asked you about it, plaintiffs' counsel
23 asked you about direct oxidation.

24 Even with all the

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1 limitations and the poor methodology in
2 the Clave study, did they document that
3 they can show oxidation of the
4 polypropylene?

5 **A.** They comment directly upon
6 that. Again, you know, oxidative
7 degradation is a chemical reaction
8 typically reserved for enzymatic changes
9 to, say, amino acids.

10 Again, as I think I stated
11 earlier, it simply involves the insertion
12 of oxygen between carbon -- you know,
13 between carbon molecules within a
14 compound. In that concept, you know,
15 polypropylene is not an amino acid or an
16 organic compound.

17 But the authors do very
18 specifically state that they were very
19 limited in how they could respond to
20 here -- they say -- they say here that,
21 you know, look, we have to acknowledge
22 that while we offer an opinion -- we
23 offer hypotheses that, maybe, what we're
24 seeing in terms of changes could be the

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1 result of oxidation. They said, look, we
2 can't confirm this hypothesis, based upon
3 our methodology or our analysis, whether
4 or not direct oxidation would actually
5 have occurred in vivo.

6 Q. So you saw they did some
7 analytical chemistry testing on a limited
8 number of samples in the Clave paper, and
9 even with that methodology, they were
10 unable to confirm their hypothesis; is
11 that right?

12 MS. THOMPSON: Object to
13 form.

14 THE WITNESS: Again, you
15 know, they -- the way that Clave
16 was set up is they looked under --
17 under a scanning electron
18 microscope, very, very high power.
19 You know, here is the pristine
20 material, here are these -- these
21 expanded small fragments of
22 material.

23 In that paper, if I'm -- if
24 I'm correct, their only definition

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1 of degradation is this doesn't
2 look like this.

3 And, you know -- and they
4 did not see changes in all
5 specimens. In fact, they saw
6 changes only in a minority of
7 those implants analyzed. And, you
8 know, again, you know, they said,
9 look, we acknowledge that we
10 cannot determine whether what we
11 observed somehow altered
12 mechanical properties. They
13 acknowledge that they could not
14 analyze implants that were in
15 women that had not gone back to
16 the operating room to have a
17 portion removed for some clinical
18 indication.

19 And, certainly, my opinion
20 would follow that as well, simply
21 the observation of surface crack,
22 the minority of specimen does not
23 establish that degradation does
24 occur.

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1 And, again, as I've stated
2 over and over, you know, that it's
3 unlikely that this could have any
4 kind of mechanical or functional
5 outcome. But, more importantly
6 is, again, you simply can't infer.
7 You can't clinically infer from a
8 paper such as this, which is just
9 sort of an observation to any kind
10 of effect that it might have when
11 it's used for its typical
12 indication.

13 BY MR. SNELL:

14 **Q.** And with regard to the
15 oxidation question, looking at the
16 article, at the bottom of Page 266, it
17 states, Several hypotheses concerning
18 degradation of polypropylene are
19 described below. None of these --

20 **A.** Counselor, I'm sorry, I'd
21 like to follow along with you.

22 **Q.** I'm sorry.

23 **A.** I'm sorry. Go ahead.

24 **Q.** You can just take it.

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1 I guess my question for you
2 is, at Page 266, you had mentioned that
3 the authors acknowledged that what they
4 were doing was basically hypothesizing;
5 is that correct?

6 A. Well, I mean, you know, the
7 authors did make an observation that the
8 material had a different external
9 appearance, albeit under only, you know,
10 very high powered scanning electron
11 microscopy. And then they start to come
12 up with some ideas that might potentially
13 explain it.

14 And they said, look, you
15 know, we've talked about several
16 hypotheses concerning whether or not, you
17 know, this represents degradation.
18 Again, their definition of degradation
19 is, this doesn't look exactly the same as
20 the pristine state.

21 And they say, you know, none
22 of these hypotheses, particularly they
23 point out the hypotheses of oxidation,
24 could possibly be confirmed in this

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1 study.

2 Q. You were asked some
3 questions about whether there is an
4 immunologic reaction, whether there's
5 severe chronic inflammation -- you were
6 asked some questions, Doctor, about
7 whether there was immunologic reaction to
8 the TVT polypropylene mesh device.

9 And I believe one of the
10 things you stated was that the randomized
11 control trials, the Level 1 evidence, the
12 long-term data do not show any type of
13 immunologic response in your opinion.

14 Is that correct or did I
15 misstate that?

16 A. No, the majority of the
17 studies, the five-year data and ten-year
18 data, you know, where they said, look, we
19 did not observe one instance of clinical
20 inflammation, chronic inflammation,
21 erosion, you know, that speaks to the
22 safety and the lack of a significant
23 adverse immunologic reaction.

24 And, again, I think just --

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1 as a scientist, as a surgeon, what I
2 would speak to distinguish between are,
3 you know, reactions that the body has
4 that are of no clinical consequence,
5 reactions that the body has that could
6 result in an adverse clinical outcome.

7 Q. Do you have Dr. Rosenzweig's
8 binder over there somewhere?

9 A. In my left hand, I have his
10 expert report. Below me, we have a
11 binder labeled, Company Documents,
12 Rosenzweig.

13 Q. Let me -- Doctor, if you go
14 back to the middle of -- I know you have
15 a lot of materials in front of you. But
16 go back to the pile. Under -- I think
17 it's under your report, where you were
18 looking at the Schimpf paper as one of
19 the exhibits. Here.

20 Can I take a look at that,
21 Doctor?

22 Let me ask you this: Do you
23 remember, you were asked a question about
24 the Wang study by the plaintiffs'

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1 counsel, if you read it and its
2 methodology.

3 Do you recall that?

4 **A.** I have the Wang study here.

5 **Q.** Okay. And you were going to
6 try to answer plaintiffs' counsel's --
7 strike that.

8 You wanted to make a
9 statement or give your impression of the
10 methodology of the Wang paper; is that
11 correct?

12 **A.** Yes. I offered an opinion,
13 and I wanted to explain my methodology.

14 **Q.** Please go ahead and do that.

15 **A.** Wang published a -- we would
16 consider -- I mean, he calls this a
17 prospective case-controlled pilot study.

18 Now, you know, within the
19 world of study design, you know, case
20 controlled studies are, by definition,
21 retrospective, not prospective. Again,
22 case controlled studies are a much lower
23 level of evidence. If we look at the
24 information that I provided here, a

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1 typical case controlled study is a Level
2 3.

3 Now, what's incumbent upon a
4 case controlled study is that you have a
5 very appropriate control group for that
6 study. And the reason for that is that
7 you're trying to minimize selection bias
8 and other forms of bias that could be
9 introduced. And so, as an investigator,
10 you have to be sure that you're picking a
11 group that is representative of your
12 control.

13 If one group has a certain
14 outcome and you're trying to look at the
15 cause for that outcome, the other group
16 needs to have similar exposure but not
17 the outcome.

18 So, for example, everyone
19 has a sling, the control group has a
20 sling with -- but lacks the particular
21 adverse outcome you're looking for,
22 whereas the affected group has that
23 outcome, itching, let's say, okay?

24 Unfortunately, for some

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1 reason, the investigators chose a control
2 group that consisted of only about seven
3 women. And, again, this was a study of
4 700 women that had undergone a procedure.
5 And these were not -- these were not
6 control women, these were women that did
7 have a clinical problem that would
8 involve a removal of the portion of the
9 mesh so it could be compared. But that's
10 not an appropriate control group.

11 So I look at this study and
12 say, you know, in all fairness, this is a
13 case series as opposed to a case
14 controlled. And, you know, that does
15 knock down the level of evidence from a 3
16 to, actually, now a Case 4.

17 And, again, the reason why I
18 make that determination is that, you
19 know, we're trying to determine whether
20 or not we can infer clinical outcome,
21 clinical importance. And, again, as we
22 go down on the scale of evidence, you
23 cannot make that inference.

24 Q. And in that study, because

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1 of the limitations of that study, can you
2 make that inference with the Wang study?

3 **A.** No. You can't make that
4 inference with the Wang study.

5 **Q.** Does a study like the Wang
6 study provide scientifically reliable
7 information on the rate of the
8 complication -- I'm sorry, the incidence
9 of complication?

10 **A.** Sure. So that's the other
11 thing that -- that, you know, a
12 well-schooled academician would tell you,
13 is that you don't calculate prevalence or
14 incidence based upon a case-controlled
15 study.

16 **Q.** And for the case series,
17 like the Abbott paper that plaintiffs'
18 counsel asked you about earlier, do those
19 also allow someone to scientifically
20 reliably speak to what the incidence of a
21 complication is?

22 **A.** In the Abbott trial, I think
23 the authors correctly pointed out that,
24 because they could not place a

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1 denominator, that you could not really
2 speak to incidence.

3 Q. Do the systematic reviews,
4 meta-analyses, numerous five-plus year
5 data that you referenced show consistency
6 in the overall safety and efficacy of
7 TVT?

8 A. They do.

9 Q. You earlier mentioned that
10 all of -- all of that data, and you cited
11 hundreds of different papers, I believe,
12 in your report, shows that the PROLENE®
13 polypropylene Type I macroporous mesh in
14 TVT for the intended use to treat stress
15 incontinence is the most biocompatible.

16 What did you mean by that?

17 A. Biocompatible, you know,
18 sort of a synonym for that, you would say
19 it shows good host tolerability. That it
20 was capability of existing within host
21 tissue with minimal to no adverse
22 reaction.

23 Q. You were asked questions
24 about the Burch and the autologous

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1 fascial sling.

2 Are either one of those
3 medical devices?

4 **A.** They are not medical
5 devices, they are surgical techniques.

6 **Q.** So the Burch and autologous
7 fascial sling are not alternative devices
8 to the TVT, which is a device?

9 **A.** They are not alternative
10 devices to the TVT.

11 **Q.** You were asked questions and
12 shown an MSDS, material safety data
13 sheet, on bulk polypropylene.

14 **A.** Yes.

15 **Q.** Is that MSDS sheet relevant
16 or clinically scientifically reliable to
17 assess whether the TVT Retropubic device
18 is reasonably safe for its intended use
19 to treat stress urinary incontinence?

20 **A.** No. That would be a
21 conclusion that you would get based
22 solely on your Level 1 levels of
23 evidence.

24 **Q.** Would the MSDS sheet even be

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1 on the levels of evidence?

2 A. They would not.

3 Q. You made -- you were asked
4 questions about cancer, sarcoma.

5 Do you recall that?

6 A. I do recall that. I do
7 believe that I addressed that in my
8 report.

9 Q. At Pages 25 and 26, it looks
10 like you addressed those issues; is that
11 correct? At the bottom of 25?

12 A. Yes.

13 Q. And in the MSDS sheet, it
14 talked about sarcomas in rats where the
15 polypropylene was in disc or powder form.

16 Do you recall that?

17 A. Yes, I do.

18 Q. And you made a statement
19 about how those data are not pertinent or
20 relevant to the TVT in its configuration
21 to treat stress urinary incontinence as a
22 knitted macroporous mesh?

23 A. Yeah. The point that I was
24 trying to make, and I don't think I

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1 stated it very eloquently, is that the
2 investigations that have looked into such
3 claims had focused on the fact that it's
4 really the material composition, it's not
5 polypropylene, per se, but the composite
6 material.

7 And additional studies were
8 done, following those initial ones, that
9 showed, really, no risk of sarcoma
10 formation.

11 I mean, again, as a
12 physician and scientist, these concerns
13 have been addressed by my peers.
14 There's -- number one, to the best of my
15 knowledge, there's never been a reported
16 case of a sarcoma occurring in a patient
17 with a TVT.

18 As I stated that, you know,
19 polypropylene has been a material of
20 choice for 40 to 50 years. And in that
21 context, there are no cases in women.
22 And my opinion was that, you know,
23 concerns about potential carcinogenesis
24 in women really are not substantiated,

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1 based upon this clinical experience and
2 the established literature.

3 Q. And you cite to a paper by
4 King and Goldman, where they did an
5 analysis of the Cleveland Clinic's use of
6 thousands of slings over a long period of
7 time.

8 Do you recall that?

9 A. I recall that paper.

10 Q. Was that one of the papers
11 you relied upon for your conclusion that
12 the TVT PROLENE® polypropylene
13 macroporous Type I mesh does not cause
14 cancer or sarcoma in its intended use to
15 treat stress urinary incontinence?

16 A. That's correct.

17 Q. Plaintiffs' counsel asked
18 you questions about roping and curling
19 and the mechanical testing of the mesh.

20 Let me ask you, you -- I
21 think you told plaintiffs' counsel this,
22 you've seen the testing where they put
23 the TVT -- or they put some kind of mesh
24 on a bench machine and stretched it?

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1 MS. THOMPSON: Object to
2 form.

3 THE WITNESS: Yes.

4 BY MR. SNELL:

5 Q. Doctor, have you seen
6 that -- have you seen testing like that?

7 A. I've seen the reports on the
8 testing like that.

9 Q. And photographs like the
10 photographs in Dr. Elliott or
11 Rosenzweig's report, where he put in
12 there a piece of mesh that was clamped
13 and it didn't have a sheath or any
14 instruments.

15 Do you recall that?

16 A. Yes.

17 Q. All right. My question to
18 you is, is that photo and the testing of
19 the mesh in that manner scientifically
20 reliably pertinent to the use of TVT and,
21 in particular, its safety in the intended
22 treatment --

23 A. It's out --

24 Q. -- of stress urinary

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1 incontinence?

2 **A.** I mean, it's outside the
3 intended use. So, no, it's not relevant.

4 And, as I stated, you know,
5 the mesh is delivered protected beneath
6 the -- a sheath. Those forces are not
7 directly exerted on the mesh itself.

8 **Q.** And is that --

9 **A.** But it's specific to the
10 tension-free design, which is where the
11 name TVT comes from, tension-free vaginal
12 tape. And that speaks to the design and
13 the method in which it's placed.

14 **Q.** And in your report, I
15 believe you talk about the importance in
16 the design characteristics of the sheath
17 and what it does?

18 **A.** Sure. I mean, that was very
19 important in the design.

20 And I would point out
21 that's, you know, -- subsequent
22 developments along the area of
23 anti-incontinence procedures all pretty
24 much kept that element of the design

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1 intact.

2 Q. And you had mentioned the
3 sheath was important, very important, in
4 your opinion to plaintiffs' counsel; is
5 that correct?

6 A. Yes.

7 Q. Why -- so is the sheath a
8 very important design element of the TVT
9 for its intended use to treat stress
10 urinary incontinence?

11 A. It's elemental in the
12 design. Without the sheath, you would
13 not have a TVT device.

14 Q. Okay. And having placed,
15 you know, well over 1,000 TVT Retropubic
16 devices, did you find the sheath to be
17 integral or elemental in the use of that
18 device to treat stress incontinence as
19 you were utilizing it?

20 A. Yes. You know, again, the
21 sheath provided several key elements.
22 One is that it protected the sheath from
23 exposure to the surrounding tissue, to
24 bacteria.

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1 But I think that, you know,
2 certainly, its greatest utility was to
3 prevent the sheath from changing its
4 configuration.

5 **Q.** Plaintiffs' counsel asked
6 you a bunch of hypothetical questions
7 about pore were collapse and curling and
8 fraying and things like that.

9 You recall seeing those
10 terms mentioned in the plaintiffs' expert
11 reports?

12 MS. THOMPSON: Object to
13 form.

14 THE WITNESS: Yes, I do.

15 BY MR. SNELL:

16 **Q.** You saw where Dr. Elliott,
17 and others, would cite to some paper by
18 Dr. Klinge in a hernia application or a
19 rabbit or a mouse study, different data
20 for those theories they were espousing,
21 correct?

22 MS. THOMPSON: Object to
23 form.

24 THE WITNESS: I'm familiar

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1 with the articles in which
2 portions of mesh, we'll call them
3 sheathless mesh, mesh without
4 sheath, were applied in those
5 applications.

6 BY MR. SNELL:

7 Q. Those types of documents and
8 that -- I'll call it data or information
9 the plaintiffs' experts relied on, do you
10 find that information scientifically
11 reliable for assessing the question, is
12 the TVT suitable or reasonably safe for
13 its intended use --

14 A. It's certainly
15 not clinically relevant --

16 Q. -- to treat stress urinary
17 incontinence?

18 A. -- to the design of the TVT
19 as it's used for its intended use, no.

20 MR. SNELL: Let's go off the
21 record. Let me see. I think I
22 may be done.

23 VIDEO TECHNICIAN: We are
24 off the record. The time is 9:05

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1 p.m.

2 - - -

3 (Whereupon, a discussion off
4 the record occurred.)

5 - - -

6 VIDEO TECHNICIAN: We are
7 back on the record.

8 BY MR. SNELL:

9 Q. And I believe, per your
10 earlier testimony, Doctor, those animal
11 studies or hernia studies, or documents,
12 are not even on the level of evidence if
13 we were trying to look to scientifically
14 reliable relevant evidence to the
15 application of treating stress
16 incontinence; is that correct?

17 A. They are -- you are correct.
18 And they certainly don't speak to the
19 safety of the procedure.

20 Q. Last question.

21 Do you have Exhibit 4?
22 Plaintiffs' counsel asked you some
23 questions about this e-mail with Kathleen
24 Feeney, and she insinuated that there

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1 was -- the statement -- here I'll give it
2 to you.

3 A. Thank you.

4 Q. -- "can you do her
5 downstairs" had to do with some type of
6 sexual interaction.

7 MS. THOMPSON: Object to
8 form. That's not what I
9 insinuated.

10 BY MR. SNELL:

11 Q. Can you tell, having had
12 time to look and think about this --

13 A. Sure.

14 Q. Tell us what, if anything,
15 you believe this pertains to.

16 A. So Kathleen Feeney had
17 referred either friends of hers, or
18 someone, when they found out what they
19 did for a living, might say, you know,
20 I'm a woman who suffers with stress
21 incontinence, I know you're in this
22 field, what -- which of your doctors
23 would you recommend that I see. She
24 would -- she would give my name and

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1 number to them. These people would come
2 to see me as a patient.

3 And oftentimes I'll say,
4 look, I'd say, how did you come to find
5 me. And they would say, you know, my
6 friend, Kathleen, referred me to you
7 because I have stress incontinence and
8 she says that you're somebody that I
9 would feel comfortable doing my surgery.

10 So in that context, the more
11 that I think about it, a friend of hers,
12 Christine, saw me, and it was a patient
13 that I was going to do her sling for her.
14 My office is on the fourth floor. OR is
15 downstairs. Obviously, I operate at two
16 different hospitals. My recollection is
17 that the friend was closest to that
18 office.

19 So the comment there,
20 clearly, to me, was, you know -- you
21 know, I talked to her about options, and
22 she kept saying, yeah, I want -- I want
23 that procedure that my friend, Kathleen,
24 has mentioned to me. And so she just

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1 might have responded, I can do you
2 downstairs.

3 Now, to the best of my
4 recollection, Kathleen Feeney had two
5 children of her own. I may have teased
6 her from time to time, that, so, hey, you
7 know you're going to need a sling, right?
8 So who are you going to have, you know,
9 do your sling? And she would say, gee, I
10 don't know, Dr. Toggia, I might have you
11 do me, or I might have Dr. So-and-so do
12 me, again, in references to doing her
13 sling.

14 Q. Did you feel harassed when
15 you were asked those questions by
16 plaintiffs' counsel?

17 A. I was very much harassed.
18 And I tried to do my best to stay as
19 professional as possible in that regard.

20 Q. The Ogah -- I want to switch
21 gears, and just, actually, get back to
22 the data.

23 A. I'm starting to feel like
24 Hillary Clinton here. But go ahead.

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1 **Q.** I want to go back to what
2 you did, reliably assessing the data.

3 The Ogah Cochrane review
4 that was marked, and I'm just referencing
5 Exhibit-5 to Dr. Blaivas's deposition,
6 does that study -- strike that -- does
7 that Cochrane review support your
8 opinions?

9 **A.** It certainly does.

10 **Q.** Does that study speak to and
11 document, in a reliable scientific Level
12 1 evidence method, of the lower morbidity
13 and the high safety to the TVT?

14 **A.** Again, The Cochrane Group,
15 which is an independent group of
16 researchers, physicians, scientists,
17 people with interest in this area, they
18 conduct independent -- it's an
19 international group of individuals. It's
20 not like there's, like, an office that
21 you would go to and this is the Cochrane
22 office. There's -- it's sort of a group
23 of individuals with common interests and
24 they perform very high -- high-level,

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1 high-quality levels of work. They are
2 widely regarded as one of the reliable
3 sources for this type of Level 1 data.

4 And, exactly, their -- their
5 conclusion is that the minimally invasive
6 synthetic slings, and, again,
7 specifically, they looked at TVT data,
8 does appear to be as effective as the
9 other procedures currently being
10 practiced.

11 Their observation was that
12 there seems to be fewer perioperative
13 complications. And they went on to list
14 specifically which ones, as well.

15 Q. Is there a more recent
16 Cochrane review that assesses the
17 usefulness, utility, efficacy and safety
18 of the TVT?

19 A. I believe earlier this year,
20 led by a gentleman by the name of Ford.
21 In 2015, they updated this, I believe,
22 that -- one of the reasons for this is at
23 the time of the original evaluation,
24 there weren't -- there wasn't a lot of

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1 good quality data on, say, laparoscopic
2 Burches. You know, again, the thing that
3 was unique about the TVT, it was
4 minimally invasive.

5 They really were hoping to
6 compare it to a more similar minimally
7 invasive. It was felt that the tradition
8 pubovaginal sling, Burch procedures were
9 more invasive.

10 So as they gathered more
11 data, they were able to compare the
12 retropubic TVT to the laparoscopic Burch.
13 At the same time, there was better
14 quality data being generated with regard
15 to transobturator approach and the mini
16 sling as well.

17 So, again, they drew a
18 comparison between the retropubic
19 midurethral sling, specifically TVT, and
20 the other two approaches.

21 Q. You mentioned, I think you
22 said, the NICE guidelines, a little
23 earlier in your testimony?

24 A. NICE, I would pronounce it

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1 NICE. It stands for the National
2 Institutes of Clinical Excellence. That,
3 actually, I believe, is a government
4 organization in the UK, a group of
5 epidemiologists and other experts that
6 seek to independently evaluate everything
7 from medication to behavioral therapies
8 across the field of medicine, as well as
9 surgical interventions.

10 And those recommendations
11 are typically conveyed to the physicians
12 that are within the UK system.

13 Q. Is that a document that you
14 reviewed and considered in formulating
15 your opinions?

16 A. I did. I mean, I hold that
17 document in the same light as I do the
18 other systematic reviews.

19 Q. I'm going to hand it to you.
20 And I want to mark it for the record.

21 But the -- you said NICE or
22 is it NICE? I'm sorry?

23 A. I'm going to call it NICE.

24 Q. The NICE guidelines says,

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1 Use procedures and devices for which
2 there is current high-quality evidence
3 for efficacy and safety.

4 And it's got a Footnote 11.

5 And it says, The guideline only
6 recommends the use of tapes with proven
7 efficacy based on robust RCT evidence.

8 What does that mean?

9 **A.** That's what I've been
10 speaking to, that, you know -- once you
11 have high-quality, high-level of
12 evidence, you can pretty much draw your
13 conclusions based on that.

14 You know, if there are no
15 Level 1 studies, you know, then you base
16 recommendations on, say, Level 2. I
17 guess for extremely rare interventions,
18 it can go lower than that.

19 But the goal is always to
20 sort of sort out the Level 1 evidence,
21 lower level evidence studies will be
22 looked at mostly to see whether or not
23 they -- they agree or are consistent.
24 But they're usually not used in the

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1 formulation of an -- of an inference.

2 Q. And they say, At the time of
3 this publication, September 2013, the
4 following met the guideline criteria.

5 And it lists TVT. I'll just
6 hand it to you.

7 A. Yes.

8 Q. Do you believe that that is
9 an accurate statement, based on your own
10 independent scientific analysis of the
11 data, with regard to the safety of the
12 TVT for its intended use to treat stress
13 urinary incontinence?

14 A. Yes. I mean, I agree with
15 the statement that, you know, they only
16 recommend the use of tapes that have had
17 proven efficacy.

18 As, I'm sure, everyone is
19 well aware, there are approximately 49
20 different mesh products available, some
21 have been very well studied, others less
22 so, some hardly at all.

23 And I think they were -- you
24 know, again, they were trying to say, we

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1 are -- we are specifically saying that
2 our recommendations and our clinical
3 recommendations should be to those that
4 have robust randomized control trial
5 Level 1 data.

6 Q. And for the TVT Retropubic
7 device, has any other device to treat
8 stress incontinence been studied as much,
9 as long and as broadly?

10 A. No. No. It is the most --
11 the retropubic TVT device is the most
12 studied anti-incontinence procedure in
13 our history.

14 I mean, obviously, it's the
15 one that I do most commonly. And that is
16 certainly based upon, you know, the
17 quality of that data.

18 Q. That NICE guideline also
19 says to use only a Type I macroporous
20 mesh?

21 A. Yes, it does.

22 Q. Is that something you
23 believe is a proper statement, based on
24 the reliable scientific evidence you

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1 agreed -- reviewed?

2 **A.** Yes, it is.

3 **Q.** Is that an opinion you
4 share?

5 **A.** I share that opinion.

6 MR. SNELL: Let's mark that.

7 - - -

8 (Whereupon, Exhibit

9 Toggia-19, NICE Urinary

10 Incontinence: The Management of

11 Urinary Incontinence in Women, was

12 marked for identification.)

13 - - -

14 BY MR. SNELL:

15 **Q.** Did you see in the
16 plaintiffs' experts' depositions where it
17 was observed and noted that even one of
18 the plaintiffs' experts, when he finally
19 decided to discuss TVT in the application
20 to treat stress incontinence, Dr. Klinge
21 noted, At present, the gold standard in
22 SUI surgery is the suburethral sling,
23 using either the tension-free vaginal
24 tape, TVT, or the transobturator tape.

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1 Did you see that when you
2 reviewed the deposition?

3 A. I did -- I did note that Dr.
4 Klinge did make that statement.

5 Q. And he also referenced Amid
6 Type I versus Type III in the Meshia
7 study, where there was a 9 percent rate
8 of erosion with the intravaginal
9 slingplasty, compared to the zero percent
10 with the classical TVT which he referred
11 to as a Type I macroporous monofilament
12 polypropylene mesh.

13 Do you recall that?

14 A. Yes.

15 Q. And you believe that the
16 TVT, the retropubic TVT, is the gold
17 standard for the treatment of stress
18 urinary incontinence?

19 A. I think that the -- yes. I
20 mean, I think that -- that synthetic
21 midurethral slings are currently the most
22 commonly practiced anti-incontinence
23 procedure.

24 I believe that the AGS

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1 membership, 95 or higher, 99 percent,
2 have done that procedure. I believe
3 within the SUFU, or maybe it's the AUA,
4 which is sort of our colleagues on the
5 urology side, it's in the mid to high
6 80s.

7 The procedure is -- is the
8 most common performed worldwide, and
9 seems to have the highest quality of
10 evidence.

11 MR. SNELL: Let's mark this
12 as an exhibit, this being the
13 statement by Dr. Klinge
14 acknowledging for the application
15 of stress urinary incontinence
16 treatment, TVT is the gold
17 standard in the macroporous
18 monofilament Amid Type I mesh.

19 - - -

20 (Whereupon, Exhibit
21 Toggia-20, Hernia Repair Surgery,
22 Volker Schumpelick, Robert J.
23 Fitzgibbons, Editors, was marked
24 for identification.)

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1 - - -

2 THE WITNESS: If I might be
3 allowed to go off the record to
4 get a glass of water, please?

5 MR. SNELL: Sure.

6 VIDEO TECHNICIAN: We are
7 off the record. The time is 9:20
8 p.m.

9 - - -

10 (Whereupon, Exhibit
11 Toggia-21, The Cochrane
12 Collaboration; Mid-Urethral Sling
13 Operations for Stress Urinary
14 Incontinence in Women (Review),
15 was marked for identification.)

16 - - -

17 (Whereupon, a discussion off
18 the record occurred.)

19 - - -

20 VIDEO TECHNICIAN: We are
21 back on the video record.

22 BY MR. SNELL:

23 Q. Doctor, I've put before you
24 Exhibit 21.

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1 Just if you can confirm, is
2 that the Cochrane review that came out
3 this year that you testified earlier
4 about?

5 **A.** This is the 2015 Cochrane
6 review on midurethral sling operations
7 that was authored by Ford and colleagues.

8 **Q.** And is that a scientifically
9 reliable Level 1 analysis?

10 **A.** The Cochrane review in front
11 of me is thought -- is Level 1
12 meta-analysis, or, in other words, it's a
13 systematic review.

14 **Q.** And in that systematic
15 review, did they look at multiple
16 randomized control trials?

17 **A.** Yes. They would look at
18 Obturator versus Retropubic. They would
19 look at whether you -- devices that were,
20 quote/unquote, bottom to top versus top
21 to bottom. Obturator, left to right,
22 right to left, or, more accurately, in to
23 out, out to in.

24 And I do believe there was

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1 some comparison that looked at types of
2 materials as it relates to cure and time,
3 hospital stay, complications, voiding
4 dysfunctions.

5 Q. As you -- strike that.

6 As you do your analysis in
7 the body of your report and you comment
8 on the high degree of efficacy that's
9 maintained with the TVT device in the
10 intended treatment of stress
11 incontinence, as well as the low
12 complication rates and the lack of many
13 late complications, even out to 17 years,
14 is that of significance to you in your
15 overall assessment as to whether the TVT
16 is safe for the intended use of treating
17 stress urinary incontinence?

18 A. Absolutely.

19 Q. Is that data inconsistent
20 with plaintiffs' experts' theories of
21 degradation, cytotoxicity and other claims
22 that there is a high rate of long-term
23 complications?

24 MS. THOMPSON: Object to

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1 form.

2 THE WITNESS: It's not
3 consistent. I'm not aware, again,
4 of any high-quality long-term
5 studies that suggest that there is
6 a significant -- any significant
7 rate -- clinical significant rate
8 of long-term complications or
9 harm, again, consistently on
10 individual bases, perioperative
11 risks, roughly in the 2 percent
12 range for each individual thing.

13 Long-term, you know, what
14 I -- what I usually sort of
15 summarize to my patients, look,
16 over the next ten years, the
17 likelihood that you might have to
18 have a re-intervention is 3
19 and-a-half percent.

20 Now, in -- if it's a
21 prolapse patient, we say to them,
22 look, you know, sometimes there's
23 a 15 to 40 percent chance of
24 reoperation for prolapse after an

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1 initial prolapse procedure.

2 These are chronic, you know,
3 conditions, as I mentioned several
4 times.

5 BY MR. SNELL:

6 Q. And in your report where you
7 analyze the literature and you state, The
8 rates of complications requiring surgery
9 are consistently less than 5 percent
10 across the TVT studies. Overall, the
11 data from these high-quality long-term
12 studies do not support the claims that
13 TVT places a woman at a significant risk
14 of long-term chronic complications or the
15 need for reoperation as plaintiffs'
16 expert suggest.

17 A. Yes.

18 Q. What did you mean by that?

19 A. Were you reading that from
20 my report?

21 Q. Yes. That was at Page 30.
22 I'm sorry, I should have told you where I
23 was reading from.

24 A. You know, again, I was

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1 trying to highlight the fact that, you
2 know, we're not -- we're not -- I wasn't
3 asked to do an analysis for nonsurgical
4 treatment to surgical treatment. We were
5 looking at comparable surgical
6 procedures.

7 So it's important to say,
8 what's the baseline? All these
9 procedures operate in the same
10 neighborhood, and, roughly speaking, they
11 have -- not only do they have similar
12 rates of effectiveness, but, overall, the
13 rates of complications are elemental.
14 They can occur with any of them.

15 Bleeding with any surgery,
16 obviously; when comparing the different
17 techniques, the risks of bleeding are
18 somewhat -- are somewhat similar.
19 Although, I think the -- the Schimpf --
20 excuse me, the Schimpf paper suggested
21 that, perhaps, the risk was a little
22 lower -- excuse me, the risk was
23 significantly lower, say, with a
24 midurethral sling compared to a Burch.

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1 Bowel and bladder injuries,
2 again, these all hovers in that sort of 2
3 to 3 percent range.

4 You know, longer -- you
5 know -- and similar things have been seen
6 with other procedures; the needle
7 suspension procedures, the autologous
8 fascial sling, what we traditionally call
9 pubovaginal slings.

10 And, again, as I read
11 through the literature and tried to come
12 up with a number, less than 5 percent
13 seemed, to me, to be a very conservative
14 number that I would feel comfortable
15 discussing with anybody with this
16 procedure.

17 Q. And did you see, in some of
18 the systematic reviews and guidelines,
19 where the Retropubic TVT midurethral
20 sling had better efficacy or subjective
21 improvement than a Burch or a
22 pubovaginal, such as Schimpf where they
23 saw higher rates of subjective
24 improvement so SGS actually recommends

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1 midurethral sling over pubovaginal sling?

2 **A.** Yes. And if I can sort of
3 qualify that.

4 So in my world, we're not
5 curing cancer, okay? We are -- we are
6 intervening in hopes of improving one's
7 quality of life. There are two ways you
8 can -- you can assess that result. You
9 know, you can simply say to the patient,
10 you know, how do you feel? Do you feel
11 like you have a substantial improvement?
12 Has this resulted in a better quality of
13 life? And that's what we would call a
14 subjective improvement.

15 Stress incontinence is a
16 complaint, it's a symptom, it's something
17 that someone complains about. That's
18 speaks to the subjective nature of
19 things.

20 It is also a condition that
21 can be demonstrated on testing; sometimes
22 as simple as saying to a woman, go ahead
23 and cough and I see if urine comes out.
24 That's done in -- a provocative stress

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1 test is done in a variety of situations,
2 sometimes with formal testing, oftentimes
3 without formal testing.

4 Or you might put a pad on a
5 woman and say, okay, you know, give me
6 100 jumping jacks. That's objective.

7 So they do tend to look at
8 both subjective and objective. We argue
9 back and forth with each other, what's
10 more important. Again, being practically
11 minded, oftentimes we'll say, you know,
12 the patient is happy subjectively, we
13 would give quite a bit of weight to that.
14 So we do break them out separately.
15 Sometimes they'll come up with a
16 composite score.

17 So, fortunately, these
18 trials were well designed and approached
19 the -- they objectively approached both
20 subjective measures and objective
21 measures in both groups.

22 Q. And you found -- did you
23 find those data reliable in order to
24 be --

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1 **A.** Well, the -- I mean, yes.
2 Many of them used the same methodologies
3 that we use in our own randomized control
4 trial.

5 MR. SNELL: No more
6 questions. Thank you.

7 MS. THOMPSON: I have some
8 follow-up questions.

9 - - -

10 EXAMINATION

11 - - -

12 BY MS. THOMPSON:

13 **Q.** First of all, in some of the
14 articles that counsel chose to ask you
15 about, I'm looking at the Ogah 2011
16 Cochrane review.

17 And that's one that you
18 relied on heavily, correct?

19 **A.** Well, it's one -- yes, it's
20 one of the studies that's -- that was
21 part of the very large pile of Level 1
22 studies.

23 **Q.** And I think we're both
24 looking at the Neurourology and

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1 Urodynamics summary of the Cochrane
2 study, correct?

3 **A.** Yes. Given this is not 900
4 pages, I'm going to say this is the
5 summary.

6 **Q.** Right. Could you turn to
7 Page 289? And I'm going to read the
8 paragraph under quality of evidence.

9 The quality of evidence for
10 the majority of trials was moderate, with
11 a minority having low to moderate levels
12 of evidence. However, the total number
13 of trials, 61, including 7,021 women was
14 high and it was possible to explore the
15 effects of different routes of insertion
16 of the tapes and different tape
17 materials.

18 On the other hand, very few
19 trials reported outcomes after one year
20 and the long-term efficacy and adverse
21 events have yet to be determined.

22 Would you agree that, at
23 least according to the Cochrane review of
24 19 -- of 2011, adverse events were yet to

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1 be determined?

2 MR. SNELL: Objection.

3 Misstates the document.

4 BY MS. THOMPSON:

5 Q. Did I not read that
6 correctly, the document?

7 A. Um --

8 Q. No. First of all -- first
9 of all, did I read that paragraph
10 correctly?

11 A. You read the paragraph
12 correctly.

13 And I just want -- in
14 forming my answer, we're talking
15 specifically about comparative trials.
16 We're not talking about long-term trials,
17 we're talking about, specifically, trials
18 that randomized women to one approach,
19 Retropubic, versus a different approach,
20 Obturator, and the duration that the
21 trial went on for.

22 This is -- this is an
23 internal comparison between different
24 types of midurethral slings.

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1 **Q.** But the report does say that
2 very few trials reported outcomes after
3 one year and the long-term efficacy and
4 adverse events have yet to be determined,
5 correct?

6 **A.** Very few studies that have
7 compared one method to the other.

8 **Q.** Okay. That's what the
9 article states, what I just read,
10 correct?

11 MR. SNELL: Objection.

12 Asked and answered.

13 MS. THOMPSON: No. It's a
14 simple question.

15 THE WITNESS: Again, the
16 comparative analysis was limited
17 to Retropubic, bottom to top
18 versus top to bottom; Obturator,
19 medial to lateral versus lateral
20 to medial; monofilament versus
21 multifilament; Transobturator
22 versus Retropubic.

23 BY MS. THOMPSON:

24 **Q.** That's all true --

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1 **A.** Yes.

2 **Q.** -- but Ogah determined that
3 the adverse events have yet to be
4 determined.

5 Reading further in that --
6 in the section that says, Conclusions,
7 implications for practice, the last
8 paragraph states, However, there is
9 little evidence about the long-term
10 effectiveness or the chance of adverse
11 events, such as tape erosions nor is it
12 clear how to treat women after a tape
13 procedure fails.

14 You would agree with me that
15 that was a conclusion that Ogah made in
16 the 2011 Cochrane review? I'm just
17 reading it.

18 **A.** That's fine. Point to it
19 again.

20 **Q.** The last paragraph under,
21 Conclusions, implications for practice.

22 **A.** Right. The last sentence
23 speaks to, you know, should you undergo a
24 midurethral sling, that these particular

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1 studies analyze -- do not answer the
2 question of what you would do subsequent.

3 Q. But I did read that
4 paragraph correctly as a conclusion of
5 Ogah in this study?

6 A. You did.

7 Q. And then in the next
8 section, Implications for research.
9 There is a need to address some of the
10 limitations of a number of the trials
11 contributed -- contributing to the
12 synthesis, particularly in improving the
13 methodology of the trials or their
14 reporting. It is highly recommended that
15 clinical trials should be reported
16 following the CONSORT guidelines.

17 Did I read that paragraph
18 correctly?

19 A. Yes.

20 Q. So Ogah, at least, states
21 that there is -- that there are
22 limitations to a number of these trials,
23 and that -- particularly, improving the
24 methodology of the trials and the

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1 reporting, correct?

2 MR. SNELL: Objection.

3 Form.

4 THE WITNESS: That's their
5 recommendations. That their --
6 they would like to see additional
7 trials that would conform to the
8 criteria that they use.

9 And, again, their primary
10 objective is that they want to
11 compare apples with apples.

12 BY MS. THOMPSON:

13 Q. And the next paragraph, in
14 implications for research, There is a
15 need for more robustly designed, good
16 quality and adequately powered randomized
17 controlled trials with standardized
18 objectives and validated subjective
19 outcomes. These trials need to have
20 long-term follow-up and adequate
21 reporting of adverse events.

22 Is that one of the
23 implications for research that Ogah lists
24 in the 2011 Cochrane review that you're

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1 relying on?

2 **A.** It's a suggestion.

3 **Q.** You'll agree with me that
4 case series can be quite significant if
5 they're reporting a new complication,
6 correct?

7 MR. SNELL: Objection.

8 THE WITNESS: I would not
9 agree with that, counselor, no.

10 BY MS. THOMPSON:

11 **Q.** So a new complication never
12 reported about, that's published in a
13 case series, you'll agree that those are
14 seen frequently in prestigious journals
15 and considered to be important?

16 MR. SNELL: Objection.

17 Foundation. Compound.

18 THE WITNESS: I mean, I
19 think -- I can tell you that in
20 the journals that I work for, they
21 are no longer interested in
22 publishing those with any great
23 frequency because they don't
24 consider them to be high

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1 quality --

2 BY MS. THOMPSON:

3 **Q.** Of a new complication, never
4 reported before?

5 **A.** Case series in general.

6 **Q.** I'm talking about case
7 series of a new complication that has not
8 previously been reported?

9 MR. SNELL: Objection.

10 THE WITNESS: Sure.

11 MR. SNELL: He's already
12 answered this and said no.

13 MS. THOMPSON: He said he
14 misunderstood my question. He
15 thought he -- I was talking about
16 case specific -- case series in
17 general, and I'm talking about
18 case series reporting a new
19 complication.

20 THE WITNESS: I'm sorry.

21 MS. THOMPSON: Those are two
22 different things.

23 THE WITNESS: I'm talking
24 about all case series, which would

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1 include the type of case series
2 that you're referring to.

3 BY MS. THOMPSON:

4 Q. Okay. And just
5 specifically, case series reporting a new
6 complication are deemed important
7 frequently, correct?

8 MR. SNELL: Objection.

9 Asked and answered.

10 THE WITNESS: Are deemed
11 important frequently?

12 BY MS. THOMPSON:

13 Q. Are frequently deemed
14 important in journals?

15 MR. SNELL: Same objection.

16 Asked and answered.

17 BY MS. THOMPSON:

18 Q. If you disagree with it,
19 just say you disagree with it.

20 A. I disagree.

21 I mean, just, again, I -- I
22 serve on the editorial board and those
23 are not manuscripts that we frequently
24 review.

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1 **Q.** Okay. Let's look at
2 Schimpf, another one of the articles that
3 counsel chose to ask you about and that
4 you relied on for your opinions, correct?

5 **A.** That is correct.

6 **Q.** Let's go to the -- to Page
7 71.E18.

8 **A.** I'm sorry, obviously, I'm
9 not able to predict what you're going to
10 ask me next, so I don't have it.

11 **Q.** I'm going to ask you about
12 the articles that --

13 **A.** No, I'm just asking for
14 permission to go off record so I find
15 that article.

16 **Q.** It shouldn't take you that
17 long.

18 **A.** No, I don't -- I'm just
19 trying to be respectful of everybody's
20 time on a Friday evening.

21 **Q.** Do you have Schimpf in front
22 of you?

23 **A.** I do.

24 **Q.** Okay. If you could turn to

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1 Page 71.E18?

2 A. Counselor, I'm not sure that
3 we're back on record.

4 Q. We never went off the
5 record.

6 A. My apologies.

7 Q. And I'm reading --

8 A. I was waiting to hear that.
9 So I did not focus on your question.
10 Could you repeat that, please?

11 Q. 71.E18. And I'm reading
12 from the paragraph that begins there,
13 Limitations to the study.

14 And Schimpf states here,
15 There was also high variability in
16 reporting of numbers and types of
17 complications in trials, making analysis
18 of AE outcomes challenging.

19 And AE stands for adverse
20 events, correct?

21 A. I would agree that
22 adverse -- AE stands for adverse events.

23 Q. While many surgeons and
24 patients are interested in information

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1 about postoperative symptoms, such as
2 urgency and de novo urgency, these
3 symptoms were inconsistently reported,
4 thus limiting their analysis.

5 Additionally, data
6 concerning need for re-treatment were
7 sparse and inconsistent, limiting our
8 ability to draw any conclusions on this
9 important question. Complications were
10 assessed at different time intervals
11 among different trials, and sometimes
12 later trials reporting secondary analysis
13 did not update longer-term AEs. The vast
14 majority did not use a standard
15 classification for complications, such as
16 the classification system of Dindo, et
17 al.

18 Did I read that correctly
19 about Schimpf's conclusions regarding the
20 reporting of AEs?

21 MR. SNELL: Objection.

22 Misstates.

23 Go ahead.

24 MS. THOMPSON: I just asked

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1 if I read it correctly.

2 BY MS. THOMPSON:

3 Q. Did I read it correctly,
4 Doctor?

5 A. You did, counselor.

6 MR. SNELL: You said
7 conclusion. So I'm going to
8 object. That's my objection.

9 BY MS. THOMPSON:

10 Q. Are you familiar with the
11 Brubaker paper that was published
12 recently that was critical of two of the
13 randomized surgical trails for urinary
14 incontinence?

15 MR. SNELL: Form. Vague.

16 THE WITNESS: Dr. Brubaker
17 is so prolific, I don't know which
18 one you're talking about.

19 BY MS. THOMPSON:

20 Q. The title is, Missing Data
21 Frequency and Correlates in Two
22 Randomized Surgical Trials for Urinary
23 Incontinence in Women.

24 A. I'm not familiar with that,

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1 no.

2 Q. So you -- and it's in the
3 IUJ, do you read that journal that you're
4 the editor of?

5 A. I read that journal. I
6 can't tell you I read everything that's
7 published within that journal.

8 Q. Would that have been
9 something interesting to you, to
10 determine that two randomized surgical
11 trials had missing visits and data
12 increasing with time?

13 MR. SNELL: Objection.
14 Calls for speculation.

15 THE WITNESS: All -- all
16 clinical trials suffer from that
17 occurrence.

18 BY MS. THOMPSON:

19 Q. At least somebody at the IUJ
20 thought that was significant enough to be
21 published, correct?

22 MR. SNELL: You're asking
23 him to comment on something that
24 he doesn't recall seeing? If

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1 you've got it --

2 BY MS. THOMPSON:

3 **Q.** You can answer.

4 MR. SNELL: If you've got
5 it, print it out and put it on the
6 record. I don't care. But don't
7 ask him to speculate.

8 BY MS. THOMPSON:

9 **Q.** You can -- you can answer
10 the question.

11 **A.** It was published, so an
12 editor felt that it was worthy of
13 publication.

14 **Q.** Are you aware of
15 publications reporting inflammatory
16 tumors associated with the TVT?

17 MR. SNELL: Objection.
18 Form. Foundation. Associated.

19 THE WITNESS: I'm sorry, I'm
20 not familiar -- I'm not aware of a
21 publication that makes -- makes
22 that claim, no.

23 BY MS. THOMPSON:

24 **Q.** Have you ever researched to

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1 see if there are benign inflammatory
2 tumors associated with TVT?

3 MR. SNELL: Objection.

4 Relevance.

5 THE WITNESS: In the
6 research that I did in formulating
7 my opinion, I did not come across
8 such an article.

9 BY MS. THOMPSON:

10 Q. What is your definition of a
11 medical device?

12 A. A medical device, I would
13 consider to be -- I think in the United
14 States devices need to be approved by the
15 FDA and the -- excuse me, the specific
16 indication for that device needs to be
17 stated.

18 Q. You've used the word
19 "approved" several times today.

20 Do you mean cleared?

21 A. I suspect that I mean
22 cleared. To me, approved, cleared.

23 Q. And so you're not claiming
24 to be a regulatory expert, correct?

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1 **A.** I'm familiar with the
2 regulatory process, probably more so than
3 the average citizen.

4 **Q.** And, yet, you don't know the
5 difference between cleared and approved?

6 **A.** I'm saying that I use both
7 terms interchangeably.

8 **Q.** So those two terms are
9 interchangeable in your mind?

10 **A.** I mean, approved, to me,
11 means it's approved for use.

12 **Q.** Is the answer yes?

13 **A.** I consider them in the
14 same -- in the same light.

15 **Q.** I'm going to read you the
16 World Health Organization definition of
17 medical device and ask you if you would
18 agree with that definition, okay?

19 **A.** Okay.

20 **Q.** Medical device means any
21 instrument, apparatus, implement,
22 machine, appliance, implant, reagent for
23 in vitro use, software, material or other
24 similar or related article intended by

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1 the manufacturer to be used alone or in
2 combination for human beings for one or
3 more of the specific medical purposes
4 of...

5 Does that sound like a
6 definition of medical device -- device
7 that you would agree with?

8 MR. SNELL: Objection.
9 Foundation.

10 THE WITNESS: I'll take what
11 you say at face value, counselor.
12 That sounds like a reasonable
13 definition.

14 BY MS. THOMPSON:

15 Q. Were PROLENE® sutures
16 cleared by the FDA?

17 A. I don't believe that
18 PROLENE® sutures, per se, are considered
19 a medical device.

20 Q. That wasn't my question.
21 My question was, were
22 PROLENE® sutures cleared by the FDA as a
23 medical device?

24 A. I thought that's what I just

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1 said. I mean, I don't know. I'm not
2 aware that they are, A, categorized by a
3 medical device. If they were categorized
4 by a medical device, I would assume they
5 were cleared. But I don't know what
6 category sutures fall into.

7 Q. I'll represent to you that
8 sutures -- PROLENE® suture was cleared by
9 the FDA as a --

10 MR. SNELL: That is a total
11 misrepresentation.

12 BY MS. THOMPSON:

13 Q. -- approved by the FDA as a
14 medical device.

15 MR. SNELL: It was approved
16 as a drug by the FDA, found to be
17 safe and effective. You know
18 that's a blunt misrepresentation
19 to the witness. And then
20 re-categorized as a device.

21 MS. THOMPSON: Forgive me.
22 It was re-categorized as a device.

23 BY MS. THOMPSON:

24 Q. Would a suture fit the

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1 medical device that I -- definition that
2 I just read to you from the World Health
3 Organization?

4 MR. SNELL: Form.

5 THE WITNESS: I don't -- I'd
6 have to see it again, sort of --
7 in writing, counselor. That a
8 rather complicated --

9 BY MS. THOMPSON:

10 Q. Is it a material?

11 A. A suture is a material.

12 Q. Does a suture usually come
13 with a needle attached?

14 A. It may or may not have a
15 needle attached.

16 Q. If it does have a needle
17 attached, is that an apparatus?

18 A. I would assume that it could
19 be considered an apparatus.

20 Q. Is it used for human beings?

21 A. Yes.

22 Q. Is it used for a medical
23 purpose?

24 A. Yes.

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1 **Q.** Wouldn't you agree that that
2 fits the definition of the World Health
3 Organization of a medical device?

4 MR. SNELL: Objection to
5 form.

6 THE WITNESS: The way that
7 you described it to me, I would
8 take your word that that's how it
9 is classified.

10 BY MS. THOMPSON:

11 **Q.** Okay. Thank you.

12 Did I hear you correctly
13 that you track your complications in your
14 practice using mental notes?

15 MR. SNELL: Misstates.
16 Go ahead.

17 THE WITNESS: We track our
18 complications on -- on
19 spreadsheets, on paper.

20 BY MS. THOMPSON:

21 **Q.** And we could request those
22 spreadsheets and papers that track your
23 complications?

24 **A.** I don't know that those

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1 exist beyond a certain period of time.

2 They're not published.

3 Q. And you don't have those in
4 your office that we can look at?

5 A. I'm sorry, I do not.

6 MS. THOMPSON: I have --

7 BY MS. THOMPSON:

8 Q. Oh, I have another question.

9 If I were to show you
10 internal Ethicon documents that show
11 degradation, show surface cracking, show
12 the clinical significance and show the
13 histological diagnosis of degradation,
14 would you still hold on to your opinion
15 that polypropylene does not degrade?

16 MR. SNELL: Objection.

17 Foundation. Form.

18 THE WITNESS: I would.

19 Because, again, the Level 1
20 evidence on safety would trump
21 lower levels of evidence, which
22 would include in vitro studies
23 that you're referring to or even
24 animal studies.

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1 MS. THOMPSON: No further
2 questions.

3 MR. SNELL: No questions.

4 VIDEO TECHNICIAN: This
5 concludes the deposition. We are
6 off the record. The time is 9:50
7 p.m.

8 - - -

9 (Whereupon, the deposition
10 concluded at 9:50 p.m.)

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1 CERTIFICATE

2

3

4 I HEREBY CERTIFY that the
5 witness was duly sworn by me and that the
6 deposition is a true record of the
7 testimony given by the witness.

8

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10

Amanda Maslynsky-Miller
11 Certified Realtime Reporter
Dated: October 5, 2015

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17 (The foregoing certification
18 of this transcript does not apply to any
19 reproduction of the same by any means,
20 unless under the direct control and/or
21 supervision of the certifying reporter.)

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1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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1 - - - - -

E R R A T A

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3 PAGE LINE CHANGE/REASON

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ACKNOWLEDGMENT OF DEPONENT

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I, _____, do
hereby certify that I have read the
foregoing pages, 1 - 415, and that the
same is a correct transcription of the
answers given by me to the questions
therein propounded, except for the
corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

MARC TOGLIA, M.D.

DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.

My commission expires: _____

Notary Public

Marc Toggia, M.D.

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1	LAWYER'S NOTES		
2	PAGE	LINE	
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